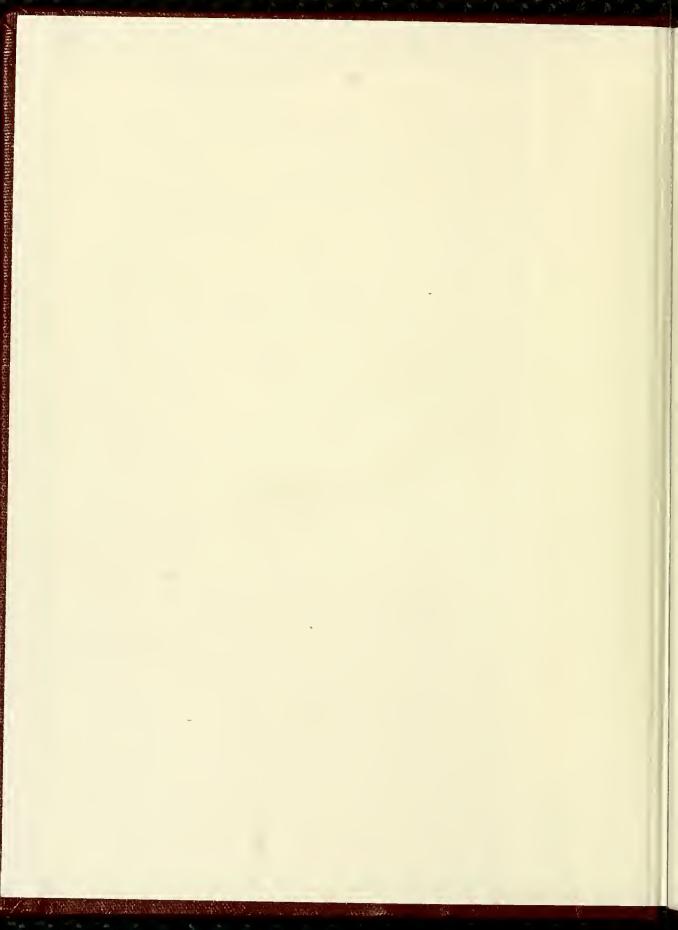
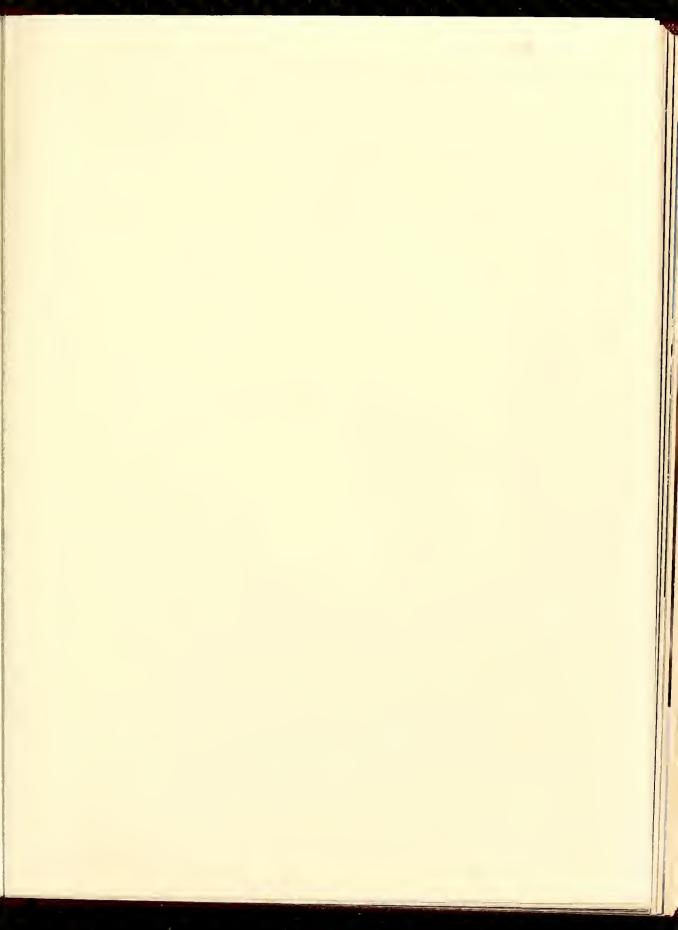
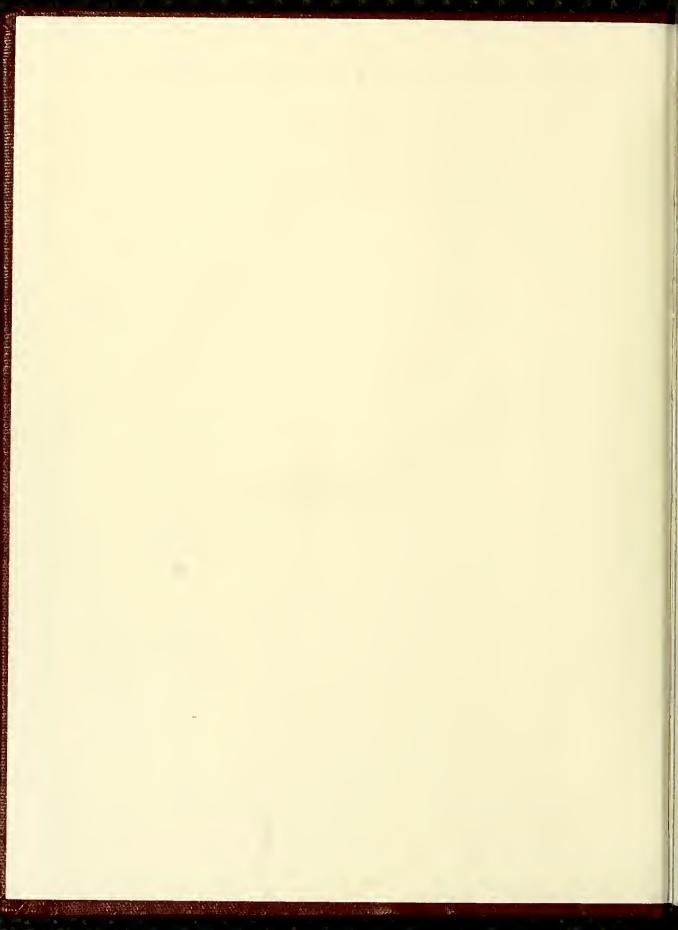
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# North Carolina MEDICAL JOURNAL

for doctors and their patients

Official Journal of the NORTH CAROLINA MEDICAL SOCIETY

January 1986, Volume 47, Number 1

#### Cochlear Implantation 1986

Patrick D. Kenan, M.D. and Joseph C. Farmer, Jr., M.D.

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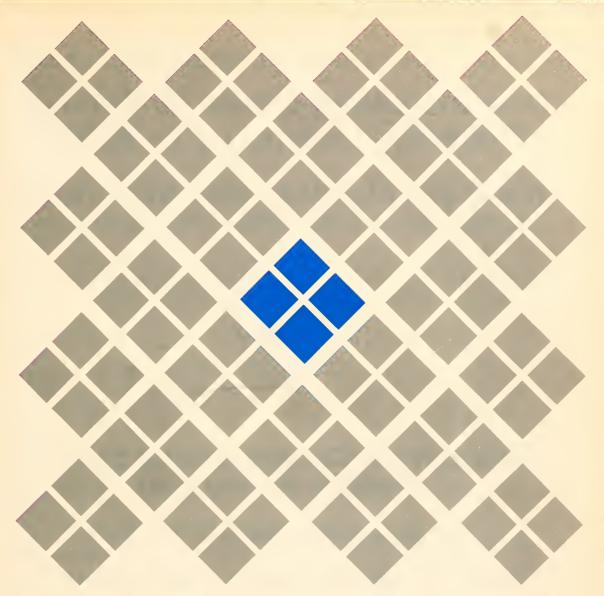
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# North Carolina MEDICAL JOURNAL

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#### About the Cover

The current status of cochlear implantation is explored in the article by Drs. Kenan and Farmer, "Cochlear Implantation 1986." The cover drawings illustrate the locations of the UCSF-Storz multichannel cochlear implant system. This device utilizes the transcutaneous transmission of electrical signals via 4 channels to the subcutaneously implanted receiver antennae, connector disc and the intracochlear electrode array inserted into the scala tympani.

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#### Cochlear Implantation 1986: An Overview

Patrick D. Kenan, M.D. and Joseph C. Farmer, Jr., M.D.

 Cochlear implants represent a giant step in improving the lives of profoundly deaf patients. Here is where North Carolina stands in the use of this new technology.

THE hair cells of the cochlea are fragile sensorineural I receptors which are highly vulnerable to a variety of diseases, high intensity noise, mechanical trauma and to ototoxic drugs. Extensive cochlear hair cell loss causes profound sensorineural deafness, but usually with varying survival of the dendrites of the primary auditory nerve fibers. Electrical stimulation of surviving fibers can provide auditory perception, and the development of cochlear implant devices to stimulate these fibers has been in progress for more than twenty years. Dr. William House in Los Angeles, Dr. Robin Michaelson in San Francisco, and Dr. Blair Simmons at Stanford University implanted single channel electrodes into the cochleas of profoundly deaf humans in the 1960s and early 1970s. These electrodes were capable of stimulating rudimentary auditory sensations, giving these deaf patients awareness of their acoustic environment and providing some of them with improved lip reading skills.

Cochlear implants have now been used in over 500 patients in the United States and were classified in 1983 by the Council on Scientific Affairs of the American Medical Association as an accepted clinical procedure in profoundly deaf adults whose deafness occurred after speech development (post-lingual deafness).2 Recently, the FDA granted market approval for the House Single Channel Implant System, manufactured by the 3M Company and developed by Dr. William House and associates. With FDA approval the 3M device may be implanted by any surgeon skilled in microsurgery of the ear. In North Carolina a number of otologists from Charlotte, Greensboro, Chapel Hill and Greenville (to name a few) are preparing or are actually offering the service, and six single channel implants have been performed to date by the Otolaryngology Division of North Carolina Memorial Hospital (personal communication).

Human voice and other environmental sounds are complex, multi-frequency signals the initial analysis of which begins by stimulation of cochlear hair cells and the corresponding dendrites of the primary auditory neurons at frequency specific locations along the cochlear spiral (the place principle). In order to provide optimum potential for speech intelligibility, a cochlear implant system must be capable of receiving, analyzing, and separating multi-

frequency sounds into different frequency bands, which are transmitted over separate channels to different electrodes lying along the cochlear spiral. These electrodes stimulate specific groups of auditory nerve fibers, which then send the signals over the existing central auditory pathways to the brain auditory cortex for higher perception and interpretation. Only multichannel implants have this potential.<sup>3</sup>

Several multichannel models have emerged and have been implanted into profoundly deaf adults with variable success in achieving intelligible speech perception, which is considered the primary goal with any cochlear implant patient. These devices have been developed in Vienna, France, Australia, Salt Lake City, Stanford, and at the University of California in San Francisco (UCSF).

The UCSF model is an 8 bipolar channel intracochlear electrode array and a four channel transmitter-receiver system developed over the past twelve years at the Coleman and Epstein Auditory Physiology Laboratories at UCSF, and now manufactured by the Storz Instrument Company, St. Lonis, Missouri. This system has been shown to be effective in achieving speech perception, and depends upon the coding strategy of an externally worn, battery powered speech processor that drives the implanted postauricular receiver by transcutaneous electromagnetic induction. A small microphone and the transmitter antennae are worn externally, behind the ear. The external components can be easily removed for such activities as bathing, swimming, physical exercise, sleeping, etc.

Duke University Medical Center is engaged in a collaborative effort with UCSF, Storz and the Research Triangle Institute (RTI) to perform FDA clinical trials of this multichannel device. The program involves a temporarily placed percutaneous cable for postimplantation testing to determine the speech processor adjustments and connections between the receiver and individual electrode channels (coding strategies) that provide optimal speech perception. These connections and stimulation patterns will vary depending largely upon each individual's pattern of auditory nerve survival, and are established using computer methods of analysis developed by Mr. Blake Wilson, Director of the Neuroscience Program at RT1, under the support of N1H project N01-NS-2356, "Speech Processors for Auditory Prostheses." Without the percutaneous testing phase, these connections have to be estimated largely by guesswork. When the optimum coding strategies have been determined, the implanted receiver is finally adjusted

From the Division of Otolaryngology, Duke University Medical Center, Durham 27710.

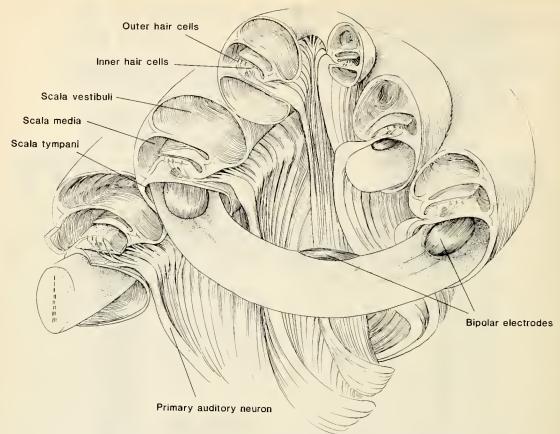


Figure 1. A cutaway drawing of the cochlea showing the UCSF-Storz multichannel bipolar electrode array lying in the scala tympani. The array is designed so that the platinum-iridium alloy contacts will lie against the medial and upper walls of the scala, thus positioning the contacts as close as possible to the dendrites of the surviving primary auditory neurons. This allows more specific electrical field stimulation patterns and improves pitch discrimination.

and the percutaneous cable is removed at a second operation. FDA approval of this device is expected when sufficient numbers have been implanted to demonstrate effectiveness and safety.

The Division of Otolaryngology of North Carolina Memorial Hospital is involved in a clinical investigation with the developers of the Australian Nucleus device (H. C. Pillsbury, personal communication). This is a 22 channel implant, programmed after implantation to utilize four or more bipolar channels. Like the UCSF-Storz device, the implant is placed through a separate hole in the cochlear capsule into the scala tympani, anterior and inferior to the round window on the promontory of the basal coil of the inner ear, and approached through the middle ear. A one stage operation is required. Of 80 Nucleus devices placed internationally, 72 are in use. The individual programming of these patients postoperatively allows an expected advantage for perception of different languages. The same may be said of the UCSF-Storz system. FDA approval of the Australian Nucleus device is expected within a few

The major limitation of the single channel implant is that

it does not take advantage of the spatial distribution and frequency specificity of the primary auditory neurons. Despite this, many profoundly deaf individuals implanted with this device have experienced a better quality of life through signal sound (bells, horns, etc.) awareness and improved lip reading skills. For adults with prelingual deafness (i.e., onset prior to speech development) who are felt to have viable primary auditory neurons, sound awareness is possible through single channel implantation or extracochlear round window stimulation. The achievement of speech understanding with any stimulation device in prelingually deaf adults is unlikely, but will probably become more feasible with future improvements in speech processing technology using multichannel implants.

The single channel device offers the advantage over the Storz-UCSF device of costs reduction (\$4,800 versus \$12,000 for the devices alone) and a one-stage versus a two-stage operative procedure. The extra cost and surgery of the multichannel system are justified by the increased probability of speech perception without visual cues and the greater likelihood of being able to use future speech processing improvements without the need to change the

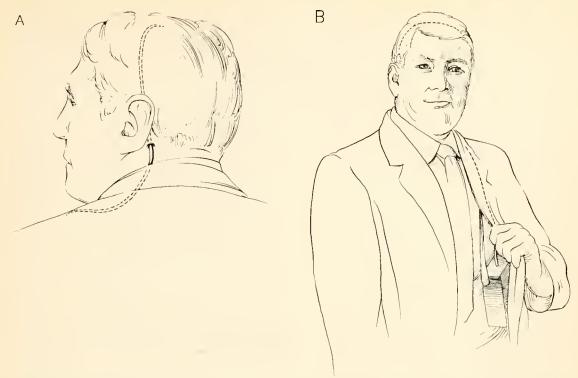


Figure 2. A. Drawing illustrating the routing of the temporary percutaneous cable in the UCSF-Storz cochlear implant system. The cable is placed beneath the scalp and exits through the skin behind the ear opposite the implant. B. A patient wearing a temporary external speech processor during the percutaneous cable phase. The cable is attached to a plug which is used for testing and for connecting to the temporary speech processor.

intracochlear electrode. With either implant, extensive preoperative evaluation and postoperative testing and rehabilitation by audiologists specifically trained in these methods are necessary.

Presently, the Storz-UCSF multichannel implants are offered only to patients with profound bilateral sensorineural deafness of post-lingual onset who are 18 years of age or older and who derive no benefit from hearing aids. Children and/or adults whose deafness began before speech onset (prelingual deafness) are not yet considered candidates because of a perceived need to first determine optimum speech processing strategies in adults who can provide the necessary feedback regarding implant function with various coding strategies. Also, subsequent temporal bone growth in children will alter the spatial relationships between the individual electrode channels and auditory dendrites necessary for optimal function. The increased incidence of otitis media in children could create greater risks of postimplantation infection with the possibility of various complications including labyrinthine and intracranial infections.

Even so, single channel devices, which are not as dependent upon spatial relationships with specific auditory neurons, have been implanted in children as a part of a research effort at the House Ear Institute in Los Angeles. Improvements in speech skills better than those obtained

with conventional hearing aids and no serious complications have been reported in the 140 children thus far implanted. Implantation in children is controversial and is considered investigational by the American Academy of Otolaryngology-Head and Neck Surgery. 1. 2

A promising approach for deaf infants and young children is the extracochlear placement of a single channel stimulating electrode on the round window or promontory of the middle ear. Indeed, Austrian and English investigators, among others, have reported that results obtained in adults with single channel devices using extracochlear placement are similar to the results obtained with a single channel intracochlear electrode. <sup>5-7</sup> These observations suggest that an extracochlear electrode would be both safe and efficacious in profoundly deaf infants and young children.

The future holds promise for further development of multichannel implants as well as likely spinoffs which will result in improved hearing aids and other devices to aid the hearing impaired and the deaf. One example is the possible development of electrode arrays for implantation onto the auditory cortex or into specific nuclei and tracts of the central auditory system for patients who have not only cochlear hair cell destruction but bilateral loss of the primary auditory neurons. At the opposite end of the spectrum, for those with less than profound deafness but who derive marginal rehabilitation through conventional ampli-



Figure 3. UCSF-Storz cochlear implant. Drawing showing patient after the second stage surgery wearing the permanent speech processor and the external transmitter antenna array which is held against the implanted receiver antenna array by magnets. The percutaneous cable has been removed and the permanent receiver inserted at the second stage procedure after data were obtained during percutaneous cable testing to determine the optimum receiver-intracochlear electrode connections.

fication, there will be implantable hearing aids that directly vibrate the middle ear ossicles or the mastoid cortex to create a more intense and less distorted acoustic signal in the cochlea. Some of these possibilities likely will become realities in the near future. One realistically may expect improvements in the speech processors of the multichannel implants which may offer even better perception of speech. Several of these technical improvements are currently being developed and tested by the scientists at the RTI Neuroscience Program in collaboration with clinical investigators at Duke University Medical Center and UCSF, and likely will be available to multichannel implant users without having to insert a new intracochlear electrode.

At the present time, single channel intracochlear implants and the Australian Nucleus device are offered through the Otolaryngology Division of the University of North Carolina. The UCSF-Storz multichannel implant is available through the Center for the Severely Hearing Impaired of Duke University Medical Center. At each institution, a battery of preoperative studies is necessary to establish that the patient is clearly a candidate for cochlear implantation. Likewise, extensive postimplantation training and rehabilitation are necessary.

Hepfner and Skelly<sup>8</sup> report that some patients implanted with the House/3M single channel device have experienced false auditory and temperature sensations due to radiofrequency interference from electromagnetic devices such as two-way radios. This interference is felt to be due to the reception and audio rectification of the emitted electromagnetic fields in the external components, for the annoying sensations ceased when the external signal processor and transcutaneous transmitter coil were removed. Similar interference could occur in the external components of the multichannel system. It is minimized by the design of the external transmitter and internal receiver coils, the use of transcutaneous transmitting frequencies outside the AM, FM and CB radio bands, and the design of the external signal processor using specific electronic filtering. We agree with Hepfner and Skelly that cochlear implant patients should be forewarned of possible radiofrequency interference and suggest that such patients be advised to remove the external components of their device when they might encounter interference such as during an electrical storm. The temporary inconvenience this might cause is, in our opinion, greatly outweighed by the improved lifestyle made possible by the implant.

Third party insurance coverage of the cost of cochlear implantation is available but variable. Many but not all health insurance carriers cover the FDA approved single channel implant. Interestingly, one third party carrier advised that, since its policies did not cover hearing aids, cochlear implantation would not be covered. This seems to be an inconsistent response since policies usually provide coverage for implantable orthopedic and cardiovascular devices. One other national health insurance company has advised that it cannot cover the postimplantation training since "we standardly do not cover charges for education or training under our group policies." This company has been advised that such postimplantation sessions include testing and device adjustments and are essential components of any cochlear implantation program. Indeed, cochlear implantation should not occur if a patient cannot undergo these sessions.

Since the FDA clinical trials of the multichannel implants have begun, many health insurance carriers have favorably responded to inquiries regarding coverage for their policyholders. North Carolina Blue Cross/Blue Shield has agreed to cover the costs of implantation except for the cost of the device itself while it is under clinical trials. Medicare and Medicaid will not cover the costs of any clinical trials. Once the clinical trials of the multichannel devices are completed and FDA approval occurs, more conventional third party coverage is expected. Interestingly, the costs of implantation of the UCSF multichannel device were covered in California while it was still in the development stage and prior to the initiation of FDA clinical trials. Coverage of the costs of the multichannel implants while under development as well as during clinical trials is gratifying, for no governmental research funds and insufficient private funds are currently available for these costs.

It is unlikely that any one insurance company will have a significant number of policyholders who would be candidates for cochlear implantation and thus incur a large cost, since the total estimated number of deaf patients who might benefit from cochlear implantation is between 60,000 and 200,000 in the United States. Patients who are likely cochlear implant candidates should definitely undergo a preimplantation review of their health insurance coverage in order to determine the existence and extent of third party coverage.

The writers welcome any inquiries from physicians, audiologists, or hearing aid dispensers regarding referral of profoundly deaf patients for possible cochlear implantation. If the subsequent evaluation indicates that any such patient is not a candidate for cochlear implantation, the possibility of benefit using other methods or instruments such as vibrotactile devices, different hearing aids or newer aids which take advantage of recent improvements in technology, and home assistive devices will be explored.

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#### Cancer in Male Veterans

Raymond W. Postlethwait, M.D.

 The experience of the Durham VAMC in diagnosing and treating cancer since it opened in 1953.

THE Durham Veterans Administration Hospital opened in April 1953. Since then, all patients admitted with a malignancy, excluding squamous and basal cell carcinoma of the skin, have been recorded in a tumor registry. The population is predominantly male. Only 23 patients with carcinoma of the cervix, uterus or ovary have been seen and a few women with cancer in other sites.

The abstracts in the tumor registry are more detailed than usually employed, containing a brief history, the positive physical findings, the results of laboratory and radiologic studies, treatment, pathology diagnosis, and follow up information. In addition to the usual objectives of a tumor registry, the purpose was to provide clinicians with a readi-

Table 1 Frequency of Primary Sites

Site	Total patients
Lip	153
Tongue	280
Floor of mouth	192
Other mouth	214
Oropharynx	249
Hypopharynx	214
Larynx	683
Esophagus	471
Stomach	356
Colon	535
Rectum	329
Liver	105
Pancreas	291
Lung	4,076
Prostate	1,762
Urinary bladder	405
Kidney	320
Brain	569
Melanoma	267
Lymphosarcoma	267
Hodgkins	250
Myeloma	217
Leukemia	464
Connective tissue	100
Other	_1,410
TOTAL	14,179

From the Veterans Administration Medical Center, 508 Fulton Street, Durham 27705.

ly accessible, easily summarized record for each primary site. The benefits of these thirty years of work are accumulating. Thirty-five analyses have been done of the registry in the last 18 months and about half of these have led to a publication.

As a current example, for planning purposes one clinician wanted a review of lung cancer for 1983. Within a day, tumor registry personnel provided basic information on the 225 patients admitted that year. Age by decade showed 113 in the 61-70 age group. The cell types were small cell 60, squamous 92, adenocarcinoma 34, large cell 24 and miscellaneous 15. The method of diagnosis was listed, the largest number (70) by bronchoscopic biopsy. Thoracotomy was performed in 56, with 40 being resectable. Irradiation was given to 117, chemotherapy to 49, and no treatment in 19 terminal cases.

The primary site of tumors in 14,179 patients is shown in table 1. Primary sites with less than 100 patients are not listed. The predominance of lung with 28.7 percent and of prostate with 12.4 percent is obvious. Five year survival,

Table 2	
Five-year	Survival

Site	Patients	No.	%
Lip	121	82	67.8
Tongue	210	47	22.4
Floor of mouth	142	47	33.1
Other mouth	162	51	31.5
Oropharynx	180	40	22.2
Hypopharynx	147	34	23.1
Larynx	497	226	45.5
Esophagus	358	12	3.4
Stomach	305	17	5.6
Colon	411	102	24.8
Rectum	249	47	18.9
Liver	85	0	0
Pancreas	240	3	1.2
Lung	2,893	162	5.6
Prostate	1,379	371	26.9
Urinary bladder	305	122	40.0
Kidney	248	62	25.0
Brain	508	47	9.3
Melanoma	197	55	27.9
Lymphosarcoma	193	50	25.9
Hodgkins	224	67	29.9
Myeloma	168	26	15.5
Leukemia	381	51	13.4
Connective tissue	93	38	40.9

Table 3 Living Veterans as of September 1984

	Veterans in U.S.A	Average age	Veterans in N.C
Total	28,027,000	52.3	657,000
Peacetime	5,240,000	44.3	124.000
W.W. I	250,000	88.3	4.000
W.W. II	10,700,000	63.3	244,000
Korea	5,237,000	53. <b>9</b>	126,000
Vietnam	8,263,000	37.7	203,000

shown in table 2, is for patients admitted before the last of December 1979. The very poor results in some lesions such as pancreas 1.2 percent, esophagus 3.4 percent, stomach 5.6 percent, and lung 5.6 percent are evident. The numbers, however, include all patients regardless of stage of disease at the time of admission.

The stimulus for this report is provided by the information in table 3 showing the number of living veterans in 1984. There is no reason to suppose the average age of veterans in North Carolina differs from the average nationally. Over half the veterans in North Carolina are over age 50 years and 37.7 percent are over 60 years. Thus,

approximately 374,000 North Carolina veterans are in the age groups where cancer risk is increased.

A knowledge of the sites where veterans will develop cancer is useful to the clinician trying to diagnose cancer at an early stage. It points out the areas where we must develop preventive and screening strategies. A knowledge of the five year survival is helpful in planning for continuing care when a diagnosis of cancer is made.

#### Acknowledgment

Appreciation is expressed to Betty Howell, director of the registry for over 25 years, Penny Ennis, current director, and Rita Rahenkamp and Mary Berini.



#### Traumatic Injuries Among North Carolinians

Carol W. Runyan, M.P.H., Ph.D.

 North Carolinians injure themselves at a higher rate than the national average. Here's how,

THE prominence of injuries as a health concern is indisputable. They cause more deaths among children over age one than the next six causes of death combined and are the leading cause of death for all persons between ages one and 45. While overall death rates due to infectious diseases have declined by 85-100% in the past 70 years, those attributable to injuries have declined by only 30%. For children, the proportionate contribution of injuries to total mortality has increased.1 Injuries are responsible for 3,681,000 years of productive life lost before age 65. This is twice the figure for the next leading cause, cancer. In fact, injuries account for 30% of the total years of potentially productive life lost from all causes. 2 Considerable acute morbidity and long term disability are also attributable to injuries, resulting in estimates of exorbitant direct and indirect costs. Because of the age groups most affected, the total annual direct and indirect costs in 1980 dollars are estimated to be \$32 billion for cancer and \$20 billion for motor vehicle injuries alone.3

Attention to injury problems has been hampered by a tendency to assume that "accidents will happen" and to attribute the problem to unexplainable, unpredictable and unalterable external factors such as "fate" or "chance," or to relatively immutable human characteristics (e.g., the so-called "accident prone personality" or risk-taking behavior patterns). Leaving aside the issues of the human component and elements of chance, it is possible to define injury in a manner that facilitates understanding of the processes by which it occurs and the development of appropriate preventive strategies.

Injury can be defined as damage to the body, usually occurring suddenly, resulting from exposure to a thermal (e.g., burns), chemical (e.g., poisoning), mechanical (e.g., falls), radiation or electrical transfer of energy or from the sudden absence of an essential agent (e.g., oxygen in drowning or heat in frostbite). Describing the event in terms of energy transfer mitigates the issue of interpreting human factors. It follows logically from this definition that intentional injuries resulting from suicide or homicide attempts be regarded no differently than injuries occurring unintentionally.

#### **Epidemiology**

Mortality. For all types of injuries, men are at two to

three times greater risk than women. Minority races in the U.S., except for Asians, have higher rates of injury fatalities than do whites. For unintentional injuries, the death rates for blacks are slightly higher than for whites, while native Americans' rates are almost twice as high. Whites and native Americans commit considerably more suicides than do blacks. However, the homicide rates among blacks far exceed those of any other group. In fact, among blacks between 20 and 34, homicide is the leading cause of death. For all but native Americans, there is an inverse relationship between income level and injury mortality. Death rates for all types except homicides are greatest in rural areas. The extent of the differences between rural and urban areas depends on the type of injury event.

In North Carolina injury is the leading cause of death between ages one and 45. The overall injury fatality rate of 70 per 100,000 population exceeds the figure for the nation. The injury death rates in this state range from 147/100,000 among the age 65 and older group to 20/100,000 for children to age 14. For whites of all ages in North Carolina the death rate due to injuries is 66/100,000, while that for non-whites is 83/100,000. The rate for men is greater than that for women (104 vs 37 per 100,000).

Morbidity. Comprehensive figures of chronic disability associated with injuries are not available. Estimates derived from the National Health Interview Survey indicate that more than 5.5 million people per year suffer injuries that chronically (for three months or more) limit to some extent their abilities to carry out major school or work activities. An additional two million are chronically unable to carry out normal activities at all as a result of their injuries.<sup>6</sup>

Injuries figure prominently as a cause of hospitalization in North Carolina. During 1980 there were approximately 59,000 injury-related hospitalizations in North Carolina. This represents an estimated rate of 1231/100,000. In the state's pediatric population to age 14, the injury hospitalization rate was 682/100,000; while for elderly patients the estimated rate was 2409/100,000. However, those in the older age groups are more likely to be hospitalized for all reasons. As a proportion of all hospitalizations, the figures for the pediatric group reveal their higher risks of injury. In those under age 14, 12% of all discharges listed an injury as the principal diagnosis whereas for those over age 45, injuries represent 6% of all hospitalizations. Unfortunately, data documenting the prevalence of injury-related chronic disability are not available.

From the Department of Social and Administrative Medicine, University of North Carolina, Chapel Hill 27514.

Table 1

Deaths and Hospitalizations Due to injuries (Event Codes 800-999) by Age in North Carolina

Age	Deaths (1983)	Rate*	Hospitalizations† (1980)	Rate*
0-14	264	20	7,370	682
15-44	2,064	74	28,418	1,256
45-64	892	77	11,107	1,189
65 +	891	147	11,770	2,409
TOTAL	4,111	70	58,665	1,231

<sup>\*</sup> Rate per 100,000 population (1980 census)

#### Costs

If the national figures for direct and indirect costs reported for motor vehicle trauma are distributed proportionately throughout the U.S. population, the total from North Carolina would be an estimated \$500 million annually. This may be overly conservative given the higher rates of motor vehicle crashes among rural populations. Medicaid and Blue Cross/Blue Shield reimbursement records for 1980 indicate that an estimated \$6.6 million was paid by Blue Cross/Blue Shield for childhood injury-related inpatient care. In 1983 Medicaid paid \$3.9 million for inpatient care for childhood injuries in the state.

#### **Etiology**

Compared with other health problems, the etiologies of injuries are generally well described. Specific underlying risk factors are sometimes less clearly understood (e.g., the contributions of alcohol, failures in product design, social factors). National figures indicate that motor vehicle incidents are the leading contributors to both injury mortality and morbidity. Other major causes are falls, drowning, fires/burns, poisoning and firearms. The age patterns indicate that motor vehicle incidents are proportionately greatest as a source of fatal injury in the adolescent and

early adult years. In contrast, falls, which contribute a relatively small share of all fatal injuries among young people, assume prominence among the elderly.

The major causes of trauma-related death across all age groups in North Carolina were, in order of frequency, motor vehicles; suicide; homicide; submersion, suffocation and foreign bodies; falls; fires and flames. A comparison of state and national statistics from 1977-1979 demonstrates that North Carolinians are at increased risk of death due to injuries, with the greatest excess risks being associated with fires and burns, motor vehicles, poisoning, firearms and drowning.<sup>1</sup>

The causes of fatal injuries differ from the causes of nonfatal trauma. For example, North Carolina data indicate that the leading causes of pediatric fatalities are motor vehicle occupant injuries; intentional injuries; drowning; and pedestrian accidents. Injury-related hospitalizations are, in contrast, the result of motor vehicle events; falls; contact with machinery, cutting and striking; and intentional trauma. Undoubtedly, the patterns for adult trauma also demonstrate some differences between fatal and nonfatal events, but those data are not currently available.

#### **Injury Prevention**

A variety of strategies are available to prevent injuries and/or their lasting effects. <sup>5, 8</sup> Countermeasures might be directed at the energy responsible for the injury (the agent), at the human hosts at risk or at the environmental context (social and/or physical) in which the transfer of energy to the human host occurs. Consistent with the public health concepts of primary, secondary and tertiary prevention, pre-event countermeasures can be directed at preventing an injury event from occurring (primary prevention), while other, secondary prevention strategies can be employed to limit the damage at the time of an event (event phase) or can reduce the severity of injuries or their outcomes in the post-event period (tertiary prevention). Figure 1 provides an example of the Haddon matrix, applied to identifying potential solutions to the problem of childhood poisoning. <sup>9</sup>

The preventive interventions first identified are frequently those using health education or other behavioral change approaches. Most of the efforts to achieve injury control

Phase		Factor		
	Human/Host	Energy/Agent	Environment	
Pre-event	Teach child to differentiate safe and unsafe substances.	Package poisons in less attractive containers.	Require childproof caps on poisonous substances.	
	Store poisons out of child's reach.	Make sure unsafe not confused with safe substances.	Package poisons less attractively.	
Event	Instruct parent in contacting poison control center.	Modify taste of substance so less likely eaten in large quantity.	Package in sublethal doses.	
Post-Event	Teach parents first aid.	Modify toxicity of substance.	Provide poison control facility.	
	Provide ipecac.			

Figure 1. Haddon Matrix Applied to Poisoning.

<sup>†</sup> Hospitalization rates are adjusted for nonreporting (19% missing). This assumes that missing data are evenly distributed across age groups.

through educational means have failed. 8 The literature concerning compliance with medical recommendations indicates that the more complex and frequent the recommended behaviors, the less likely they are to be adopted. 10 This literature suggests that injury prevention efforts requiring the minimum of human behavior change are the most likely to be successful. Furthermore, passive measures, which modify the environment or the products that people use, have shown the greatest promise for injury reduction. The packaging of poisons in childproof containers or in sublethal doses has proven much more effective in reducing childhood poisonings than safety education for parents. Similarly, the installation of airbags or automatic seat belts in all cars probably holds more promise of successfully preventing motor vehicle injuries than do efforts limited to inducing people to wear seat belts, even if by law, because there will always be some who do not comply.

Incremental and multipronged preventive approaches are often the most appropriate. In this regard, education has a useful function 1) in situations where no passive measures can be employed (e.g., use of child car seats); or 2) where the socio-political climate is not yet accepting of passive measures (e.g., the past 20 years of debate about airbags). Education may also help people develop positive health habits at early ages and may serve as a means of establishing a constituency more willing to accept or advocate the establishment of effective safety policies.

#### Roles for Health Care Providers

There are a number of important roles for physicians in preventing injuries. They range from legislative advocacy to data collection, research and patient counseling. It is important that physicians work with other professionals in developing and promoting appropriate countermeasures of all types. Many passive injury prevention strategies require legislative mandate or other changes in the regulatory system. Examples of areas where physicians have played active roles in safety legislation include development of the Poison Prevention Packaging Act, the Flammable Fabrics Act, and state child restraint legislation. While not every physician has the time to engage in major lobbying activities, keeping informed of safety issues and writing letters to representatives or serving as expert witnesses are all effective roles for physicians with limited time.

To discuss injury prevention with either decision makers or patients, health professionals must be prepared with accurate and convincing evidence. Documenting the causes of nonfatal injury cases seen in both inpatient and outpatient care is particularly important since the numbers are so large and no standardized recording mechanism analogous to a death certificate exists. Currently, this information is recorded in only 67% of North Carolina hospital discharge summaries and no standardized reporting is practiced in emergency rooms or other outpatient facilities. Consistent reporting practices to enable the documentation of injury causes (E codes) as well as injury types (N codes) within the ICD-9-CM schema would greatly enhance injury surveillance and permit monitoring of the effects of prevention programs.

While recognizing the limitations of educational methods, physicians should continue to counsel patients

with respect to safety in home, motor vehicle, recreational and occupational activities. In so doing, it is important to consider the many factors that contribute to individual behavior. Factors associated with safety behaviors include risk perceptions, cultural and economic factors, knowledge of correct safety practices, attitudes toward safety and potential environmental barriers to adhering to safety precautions. Health educators or health psychologists trained in patient behavior and behavior change techniques are frequently available in universities, health departments or hospitals to assist in developing educational interventions with the greatest likelihood of success.

It is important to develop appropriate pre and post graduate educational opportunities aimed at improving knowledge about safety hazards and options for injury control. Furthermore, research in injury epidemiology and evaluation of injury prevention measures are important to any teaching program. While major responsibilities for injury research may be assumed by those in academic settings, all practicing physicians need to participate in the case identification and record keeping processes.

Finally it is the unique role of health care providers to continue to improve emergency and other medical services for the treatment of trauma victims to reduce the likelihood of both death and long-term disabilities associated with serious injury. While activities such as improving the skills of health professionals in advanced life support are vital to this endeavor, they must not be allowed to overshadow primary prevention activities.

#### Acknowledgment

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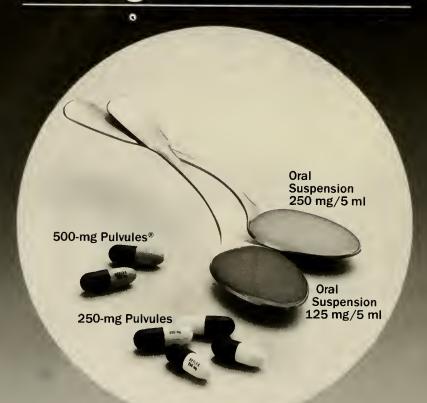
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# Herpes Simplex Virus Encephalitis: The Need for Early Diagnosis

Gail L. Shaw, M.D., and Amelia Ann Langston, M.D.

HERPES simplex virus is the most common cause of sporadic viral encephalitis in the United States. <sup>1</sup> It occurs in all age groups, from neonates to the elderly. The disease was first recognized in 1940. <sup>2</sup> The prevalence is one case per million per year. <sup>2, 3</sup> Pre-existing herpes simplex virus infection is not increased in incidence in herpes simplex virus encephalitis over the general population. <sup>3, 4</sup> The mortality of untreated herpes simplex virus encephalitis can be as high as 70% and the sequelae among survivors result in significant disability in 50%. <sup>2</sup> Because of the serious nature of the possible outcomes, early diagnosis and treatment are important.

A 49-year-old right-handed black man was taken to a hospital after a generalized tonic-clonic seizure was observed by his family. He had a 45 pack year history of cigarette smoking, drank ½ pint of gin daily and had a history of hepatitis 10 years previously but had no history of seizures. The seizure was preceded by a two-day history of dyspepsia, nausea, chest tightness and alcohol abstinence.

On arrival at the hospital, he had three more seizures and was given Dilantin 700 mg IV. About twelve hours later he again had three tonic-clonic seizures and was given Dilantin 300 mg IV. Lumbar puncture showed opening pressure 132 mm H<sub>2</sub>O (normal 100-200), protein 48 mg/dL (normal 15-50), glucose 117 mg/dL, plasma glucose 154 mg/dL (normal 75-110), white blood cells 108/mm³ of which 25% were polymorphonuclear leukocytes and 75% were lymphocytes, red blood cells 10/mm³. Other remarkable laboratory findings included creatinine phosphokinase 29,000 IU (normal 0-130) and white blood cells 24,700/mm³ (normal 4500-10,500) with a left shift. Unenhanced computerized tomography of the brain was normal. Because of his persistently abnormal mental status, he was transferred to our institution.

Physical examination revealed temperature 38°C rectally, pulse 80, blood pressure 156/90 mm Hg and respiratory rate 18/min. The patient was a muscular black man who grimaced intermittently. The general physical examination was remarkable only for right basilar rales. The patient was oriented only to self. He intermittently complained of 'feeling bad' but did not respond to commands. He had resting horizontal nystagmus. There was absence of upward gaze. Pupils were 3 mm and reactive. The optic disks were flat. The face was symmetric, tongue midline without

fasciculations, but the gag was absent. Meningismus and Brudzinski's sign were present. Motor exam revealed diffusely increased tone on the right with movement of all extremities except the right upper extremity. He withdrew to deep pain. Deep tendon reflexes were increased on the right with no pathological reflexes. Occasional lip smacking and staring spells were noted.

Repeat lumbar puncture was performed with opening pressure 165 mm H<sub>2</sub>O, white blood cells 276 (11% polymorphonuclear leukocytes, 79% lymphocytes, 10% monocytes), red blood cells 65, protein 28 mg/dL, glucose 96 mg/dL (plasma glucose 169 mg/dL). Admission laboratory findings revealed white blood cells 13,600 (81% polymorphonuclear leukocytes, 13% lymphocytes, 4% monocytes, 2% bands), creatinine phosphokinase 21,910 IU, blood urea nitrogen 11 mg/dL (normal 7-21), creatinine 0.9 mg/dL (normal 0.7-1.4), room air arterial blood gases: pH 7.41, pO<sub>2</sub> 58, pCO<sub>2</sub> 41, Dilantin level 10.2 μg/ml (therapeutic 10-20 μg/ml). The patient was given phenytoin 600 mg IV and the level rose to 19.2. He continued to have episodes of staring.

A repeat lumbar puncture the day following admission showed protein 39 mg/dL, glucose 39 mg/dL (plasma glucose 149 mg/dL), 109 white blood cells (8% polymorphonuclear leukocytes, 89% lymphocytes, 1% monocytes), 228 red blood cells. An enhanced brain computed tomogram was normal and the electroencephalogram showed right temporal lobe periodic lateralizing epileptiform discharges. The patient was started on acyclovir, and an open brain biopsy was obtained the following morning. Immunofluorescence of the biopsy was positive for herpes simplex virus.

The common presenting features of herpes simplex virus encephalitis include headache, lethargy, fever, malaise and nausea with vomiting. The course may be gradual or involve a rapidly progressive loss of consciousness leading to coma in a mean time of six days and death in a mean of 11 days.<sup>2</sup> Seizures occur in over 50% of patients, and focal cerebral dysfunction, including dysphasia, weakness, paresthesias, hypothalamic dysfunction, memory deficit and personality change,<sup>2</sup> is evident in 75% of patients. The temporal and frontal lobes are most commonly involved in herpes simplex virus infection.

The virus is carried in the upper airway, skin or lung and has been found in the olfactory tract.<sup>3</sup> The viral replication results in multifocal cell injury and coalescent areas of tissue necrosis.

The pathologic changes of herpes simplex virus en-

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cephalitis can produce characteristic localizing findings on noninvasive studies, although none are pathognomonic. The cerebrospinal fluid characteristically shows a mononuclear pleocytosis, elevated protein (usually less than 200), normal opening pressure, normal glucose and variable red cell count. 6 Serologic testing is of minimal value in the course of disease and is plagued by low sensitivity. Radioimmunoassay for herpes simplex virus antibodies in the cerebrospinal fluid shows promise in small studies, but sensitivity is only 50% within the first ten days of illness. The most sensitive noninvasive study is the electroencephalogram: periodic unilateral or bilateral spike and slow waves localized to one temporal lobe are suggestive of herpes simplex virus encephalitis in the appropriate clinical setting. This pattern has also been seen in other conditions including focal cerebritis, brain abscess, tumor, infarction and neurosyphilis. The largest series analyzing noninvasive studies in herpes simplex virus encephalitis reported 81% of patients with abnormal electroencephalograms with 65% showing the spike and slow wave pattern described above.6 In the same series, enhanced computerized tomography brain scans showing focal low attenuation within the medial, temporal or insular cortex, with or without focal hemorrhage, were observed in 59% of patients.<sup>6</sup> Abnormal brain computed tomogram prior to therapy was associated with particularly poor clinical outcome in at least one large series.8 Whitley et al. found localizing findings in 82% of 113 patients with biopsyproven herpes simplex virus encephalitis using the combination of electroencephalogram, enhanced computerized tomography of the brain and radionuclide brain scan. Similar localizing findings were seen in 25% of patients with other diagnoses.6

Brain biopsy remains the only definitive diagnostic procedure for herpes simplex virus encephalitis. Mortality of biopsy is approximately 0.5%, with a complication rate of approximately 5% and a false negative rate of about 5%. The most compelling reason for biopsy in suspected herpes simplex virus encephalitis is the potential yield of alternative treatable diagnoses. In the NIAID collaborative study of 132 patients with clinically suspected herpes simplex virus encephalitis supported by electroencephalogram, computerized tomography of the brain

or technetium brain scan, 23% of patients eventually proved to have other diseases, many of which were treatable. Specific new diagnoses found in this setting included bacterial cerebritis or abscess, disseminated cryptococcus, tuberculosis, toxoplasma infection, subdural empyema and tumor. 8-10

It is clear that early diagnosis and institution of therapy are essential in herpes simplex virus encephalitis. Morbidity and mortality are directly related to the level of consciousness at the time of institution of treatment.9 Ara-A was the first drug clearly shown to have efficacy against herpes simplex virus encephalitis. Acyclovir has recently been shown to be superior to Ara-A with a 19% mortality rate in the acyclovir group versus 50% in the Ara-A group. Acyclovir therapy also decreased morbidity with 56% of the acyclovir group returning to normal activity within six months versus 13% of the Ara-A group. Since acyclovir interferes only with viral DNA<sup>3</sup> it avoids the large volume requirement of Ara-A therapy, which can increase cerebral edema and hematologic toxicity. In cases of suspected encephalitis, rapid noninvasive evaluation with electroencephalogram and enhanced computerized tomography brain scan, followed by brain biopsy as indicated, should not be delayed.

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#### **Invited Comment:**

David T. Durack, M.D.

The differential diagnosis between focal encephalitis caused by herpes simplex virus and nonfocal viral encephalitis or aseptic meningitis is difficult. Herpes simplex encephalitis is rare but has high morbidity and mortality, demanding early treatment with acyclovir. On the other hand, aseptic meningitis is common but not treatable. Likewise no treatment is presently available for the less common nonfocal viral encephalitides. The physician must weigh the pros and cons of possible over-investigation with expensive and/or invasive tests such as the computerized tomography scan and brain biopsy while avoiding failure to diagnose herpes simplex encephalitis.

Our approach at Duke is to keep the possibility of focal encephalitis in mind at all times, while recognizing that it is rare. When one or more findings in the history, examination or investigation point to focal disease, we favor biopsy if computerized tomography and/or electroencephalography confirm a focal lesion. (Brain scan, while approx-

imately as sensitive as computerized tomography and electroencephalography, is seldom necessary today if the other two tests are employed.)

We favor biopsy after proper evaluation in most cases, rather than empiric treatment with acyclovir, for two main reasons. 1) The disease(s) under consideration are potentially very serious, making accurate diagnosis highly desirable. This becomes especially important if the patient has a poor outcome, for example remaining in coma or spending a long period in an intensive care unit. 2) Biopsy will reveal a small but significant subgroup of patients with other, treatable diagnoses.

This approach does not preclude the possibility of choosing blind acyclovir therapy without biopsy for selected individuals. However, it is important to remember that treatment with acyclovir is specific for only one group of DNA viruses; it is *not* analogous to broad spectrum empiric antibiotic therapy for suspected bacterial infection.

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# What's New in the Management of Streptococcal Pharyngitis?

Floyd W. Denny, M.D.

With rheumatic fever virtually eradicated, efforts in the strep pharyngitis
area turn to faster diagnosis and management of the resistant cases.

SEVERAL articles recently published in the medical literature have prompted this brief review of what is new in the management of streptococcal (strep) pharyngitis. After the discovery in the early 1950s that penicillin treatment prevented the subsequent occurrence of rheumatic fever, few changes took place in the management of strep pharyngitis for over two decades. The virtual disappearance of rheumatic fever from developed countries in the last ten years dictates that the approach to the management of pharyngitis be reevaluated. Pertinent to this reevaluation are articles that address 1) the reevaluation of the effect of treatment on the clinical course of strep pharyngitis, 2, 3 2) the demonstration of the effectiveness of the rapid detection of streptococcal antigens as a method of diagnosis, 4-8 and 3) new treatment strategies in eradicating the streptococcal carrier state.<sup>9, 10</sup> All of these have changed substantially the way patients with pharyngitis should be managed in 1985.

The reason for the great decline in rheumatic fever in the United States is not clear but the widespread use of penicillin treatment of strep pharyngitis probably played a major role. Therefore, the prevention of rheumatic fever remains a primary goal of treatment. In this regard, the recent emphasis on the relationship of treatment to the clinical course of strep pharyngitis is of interest and importance. Although it was shown clearly over 30 years ago that treatment was effective in making patients feel better, this was of secondary importance to the need to prevent rheumatic fever.<sup>11</sup> The impreciseness of the clinical diagnosis of strep pharyngitis led to the use of the throat culture for more exact diagnosis, thus delaying the start of treatment in some cases. In the socioeconomic climate of today the renewal of interest in the effect of treatment on the course of strep pharyngitis suggests that antimicrobials could (and probably should) be used more freely to "cure these patients" sooner. A few words of caution are in order here. Strep pharyngitis is an acute, self-limited disease when no treatment is given, and antimicrobial treatment can reduce the time of recovery only when given early in the course of illness and then by only one to two days at best. Since many patients who present to a physician with pharyngitis have a viral illness, it seems wise to treat immediately only those patients in whom the diagnosis of a strep infection seems clear. The physician should continue to attempt to confirm the diagnosis of a strep infection by laboratory means and treatment should be initiated or continued only in those patients who are culture (or antigen) positive.

The discovery that the antigens of group A streptococci can be demonstrated by rapid methods may well revolutionize the approach to the patient with pharyngitis. These tests are predicated on the ability of specific antiserum to react with antigens extracted from throat swabs, all within just a few minutes. Published studies show that these tests are reasonably sensitive and specific and have good positive and negative predictive values. 12 Problems do exist, however, in their use. They fail frequently to identify those patients who are harboring small numbers of streptococci and on occasion do not identify patients harboring large numbers of streptococci. They are more expensive than sheep blood agar plates, and in practices without the services of a laboratory technician performance time is a practical consideration. Because the rapid tests have not withstood the "test of time" they should not be used just yet as the sole method of making the laboratory diagnosis of strep pharyngitis. It would seem reasonable for the physician caring for a patient with pharyngitis to take two swabs from the throat, one to be used for rapid diagnosis and the other for a throat culture. If the rapid test is positive the second swab could be discarded. If the rapid test is negative, a sheep blood agar plate could be charged in the usual way and the culture results obtained the next day. The patient could be managed according to the results of both

In general, the usual methods of treating strep pharyngitis are effective in eradicating the causative bacterium from the throat. In a small proportion of patients the streptococcus is not eradicated and in a few patients positive cultures persist in spite of repeated treatments. Persistently positive cultures can be troublesome because they can occasionally be associated with recrudescences of symptoms, but more importantly because they can mislead the physician when obtained during non-streptococcal respiratory illnesses. Rifampin (20 mg/kg in one dose/day or 10 mg/kg in 2 doses/day) for the last four days of penicillin treatment has

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been shown recently to be effective in eradicating the carrier state. 9, 10 Although this has not been used extensively up to the present it is recommended that it be tried in troublesome cases.

The reader is admonished to follow current literature carefully so that as these and newer methods of strep pharyngitis management become more firmly established they can take their proper place in primary care practices.

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# "Partial Retirement" in a Group Medical Practice

Leif C. Beck, LL.B. and Joseph W. Gallagher, J.D.

• A how-to article for a group practice soon to face the full or partial retirement of a member.

WHETHER a medical group practice comprises two partners or twenty members, a disparity in ages may lead to a common, but difficult, problem. How can a group permit its physician-member to phase down his or her level of activity at some senior age while still being fair to the other members? The question is arising more and more often these days, either because a member actually proposes to partially retire or because the membership wants guidelines for whenever the request might arise.

There is no simple, all-inclusive formula for solving the problem. Group practices are, however, well advised to consider it far ahead of any specific request; once a member seeks partial retirement status it is difficult to disinterestedly decide on his or her arrangements. We see physicians preferring to phase down as early as age 55 these days, and even earlier in case of illness, so the issue should be faced now.

Once a policy is decided upon, it should be formally adopted in writing in some manner. The rules might be added to the legal documents, whether partnership agreement or corporate employment contracts, though we sometimes recommend a less rigid form. A written resolution, adopted at an official partnership or shareholder meeting, might be voted upon and then become part of the group's overall "Summary of Members' Benefits." Since such papers tend to become lost by some physicians, we have also suggested that group managers calendar a reminder to redistribute the summary each year.

#### How to Phase Down?

The concept of partial retirement or practice ''phase-down'' defies any simple formula largely because there are so many variations by which a doctor might scale down his or her work. One physician might choose to go full-time for six months and be absent for six months, or four months on and four months off, etc. Another might work full-time but increase vacation to ten, twelve or more weeks.

Still another doctor would work full-time but only three days a week with or without being on a full (or reduced) night and weekend coverage schedule. Or he/she might elect to work the regular schedule but only until two o'clock

each afternoon. Many physicians prefer regular work schedules except for dropping night call and/or weekend coverage. And to compound things more, some physicians try to achieve a combination of the above alternatives. One can hardly set out a set of rules that will respond automatically to such a plethora of possible circumstances.

#### **Overall Policy**

Generally, there are three policy positions that a practice can adopt as to partial retirement. First, a fair number of groups take an all or nothing approach to retirement (i.e., no partial retirement permitted) on the philosophy that a doctor must either accept all aspects of practice, negative as well as positive, or else be replaced by someone who will. Second, other groups permit a doctor to automatically drop off specified practice activities once he or she has attained a specified age and/or number of years' service; the actual progression of permitted phase-down tends to vary depending on the practice specialty, the group's range of obligations, etc. And third, a practice might allow any "eligible" member (i.e., one with the requisite years of age and/or service) to propose his or her reduced activities and the corresponding arrangements (including pay) for the other partners to accept or reject by actual vote.

We tend to prefer this last approach for many group practices. It forces the senior member to identify how he or she will actually function during a phase-down period, while it allows the ongoing members to evaluate its effect on their practice. If the plan will impose too large a burden, they might reject it or perhaps accept it at a reduced salary level sufficient to support hiring a new young doctor for the practice.

#### **Compensation Problem**

It is virtually impossible to decide on a reduced pay level that will perfectly reflect a member's reduced activities. If, however, the group keeps track of each member's production (either patient charges or collections therefor), the phase-down might be compensated quite comfortably. Allowing the partially retired doctor to be paid an agreed percentage of production will in many cases permit his or her compensation to constantly self-adjust to the selected work level.

Even productivity payment might, however, fail to recognize a senior doctor's reduced usefulness to his or her group. The classic example involves night call and/or

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weekend coverage obligations which physicians invariably seek to drop at some senior age but which might have little direct effect on production of income. And the younger doctors sometimes object that any corresponding increase in their call obligations is totally unacceptable. Even in productivity payment situations, then, some degree of group consent may be necessary to accommodate a senior member's desire for partial retirement.

#### The Application Format

If a group decides upon a format of advance application and partnership approval of one's phase-down plan, the process for handling it should be well spelled out. We usually recommend that he or she must submit the plan well in advance of the requested partial retirement date. Six to twelve months will in most cases provide sufficient time for the ongoing group to consider its work level and, if appropriate, recruit a new physician. The request should be in writing indicating exactly what schedule reduction is sought, what will be the accompanying reduced salary or partnership share and what the applicant plans to do during the time off.

The format might then call for the rest of the members to vote on the request within a specific time period. That approval might be by a simple majority (or perhaps two-thirds) vote or, for small groups, by unanimous consent. The request should only be accepted on a one-year basis to enable the ongoing fully active partners to evaluate the situation as it unfolds. This is particularly important where a number of members are at or near the age and service levels at which the reduced activity would be allowed.

The senior doctor can, of course, continue the arrangement by applying for successive one-year partial retirements, each of which must be subject to the same membership approval rules. He or she can thus continue the phase-down process year by year, if so desired, but the fear of rejection might dissuade another year's extension if his/her usefulness or capabilities are declining. Some groups establish a maximum limit of three or five years' partial retirement, followed by automatic full termination, to prevent the arrangement from becoming permanent.

Finally, as a condition of taking on such reduced activity, the partially retired physician might be required to sell back his or her interest in the corporation or partnership. If a doctor is not fully involved in all aspects of the practice, perhaps he or she should not be permitted to participate in decisions that would substantially affect it.

#### Final Retirement Pay-Out

In implementing a partial retirement program, there may be concern how (if at all) to treat the established arrangements for paying out a member upon full and final departure from the practice. For example, if a physician were to reduce his activity by one-half and thereafter die or completely retire, should his separation pay be based on the income he received while working at the reduced level? Such a result will often be basically unfair, for his ownership interest in practice assets is the same whether he departs in stages or all at once.

To overcome this possible problem, we sometimes recommend that the employment or partnership agreement base the senior doctor's severance pay on the salary or share and upon the accounts receivable and goodwill as they existed in the last year before the phase-down. This would, in effect, "freeze" the retirement pay-out until death or full retirement.

#### Conclusion

Partial retirement can create very difficult, sometimes embarrassing and divisive, problems even for compatible group practices. They become more difficult, however, if one or more members seek a phase-down and there is no format for handling their desires. Hence, we urge creating a set of guidelines early on — hopefully years before anyone might be prepared to act under them.

As a group of professionals who have worked to build a successful practice over many years, the members owe an obligation to adapt to each partner's special needs so long as they will not disrupt the ongoing practice. Concessions can be made if they will not cause real difficulties and if making them helps all the partners maintain a continuing level of satisfaction.

#### North Carolina Medical Journal

#### Features for Patients

January 1986

#### Why Marital Therapy?

Linda Rubin, N.C.C.M.F.T.

Why invest considerable time and money; why subject yourself to the painful uncovering of intense feelings to "save" your marriage? These are important and complicated questions people considering marital therapy need to answer before committing themselves to the process.

Like most important commitments, there is no guarantee of outcome and no simple answer to the question "why bother?" that will apply to everyone who considers treatment. There are, however, some compelling reasons to take a troubled relationship to the professional marital and family therapist.

Although it may seem trite, I believe that the intimate and powerful relationship between marital partners creates a structure which enhances the emotional well-being of the individual partners, provides a model of intimate relationships for the children, and creates the atmosphere for the nurturance and socialization of our future adults. In an important way, our marriages, and subsequent families, define our destinies as humans in this life.

It's troubling to consider the divorce rate, to see that half of the attempted morriages do not bring about enough emotional satisfaction to continue. It is of concern to look at how many children experience the depression, guilt, despair of abandonment, and anxiety that attend the most "civilized" dissolution of the marital and family bond. When their most primary relationships are conflicted or temporary or both, these children do not know what to count on as an angoing, constant structure oround which to experience and organize themselves as they ore maturing.

Why bother? Because marriage and family are important and, further, because dissolution of the family is painful.

On the other hand, a seriously troubled marriage and family are also painful. Let us look a moment at the arguments in favor of ending a morriage that we have thought about as a primary and necessary one.

Relationships characterized by the use and abuse of human beings, regardless of age, certoinly are not in the best interests of the participants. The ethics committee of the American Association of Marital and Family Therapy suggests that when it is clear from professional evaluation and consultation that a marriage compromises the emotional or physical well-being of husband, wife, or children, and when the destructiveness is irreversible without more effort than either partner can put forth, then separation or divorce is usually the

best alternative.

It seems straightforward to say thot some marriages should end: marriages that are "hate matches" rother than "love matches" or partnerships that can not be negotiated to meet the most important dependency and security needs of the partners.

As we consider the question "why bother?" we need to look at the issue of motivation. Regardless of the workability of any relationship, the partners both must want to commit the time, money and energy to the process of marital treatment. In addition to believing that marriage is important, it is necessary that both partners be willing to look at themselves, their personal history and their relationship to one another. They must be committed to this process even in the absence of a guaranteed outcome. In my experience partners rarely commit to treatment if the marriage is already over for one or both of them. Attempting treatment without mutual agreement does not work.

#### **Realistic Expectations**

A couple seeking help from a competent marital therapist can expect to get assistance in the following areas:

1. Communication Skills. Development of clear communication so that the message sent by one partner is the message received by the other.

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This skill is essential to the pracess of understanding the marital prablems. A cauple will need to look at the intent of each message and its impact on the partner. The therapist will help the cauple learn the cammunication skills necessary far the clarification and definition of prablems.

2. Definition of the Problem. The therapist will assist the cauple in understanding the behaviors and attitudes that are causing the morital distress. The therapist will explare with the cauple their thaughts and feelings about the identified marital problems. The therapist and cauple will construct an understandable explanation for the discontent.

3. Conflict Resolution Skills. The cauple must consider passible alternative ways to behave in, to think about and to experience their marriage. The therapist will help them to negatiate a new marital contract between them, one that will better suit their individual needs and wants. This wark will be done in the context of what is realistic and available in the marriage at that time.

4. Identification of Strengths. The therapist will help the couple to identify the strengths in the marriage. It will be useful to remember the good times and good feelings that get lost in the face of conflict.

5. Understanding the Potient. It is realistic to expect the competent therapist tatake the time taget individual and marital histories fram the cauple. Bath persons in a marriage have families in which they were raised. We all bring attitudes, values and experiences fram that family into our marriages. It is important for the therapist, and the spauses, to review the years that have came before the marriage in addition to the years of history since the marriage. The ways in which aur past is affecting the present is impartant. Knawing our history and sharing it with aur spause is an experience that brings about claseness.

6. Knowing Personal and Prafessianal Limitations. It is realistic to expect the therapist ta know his/her awn his-

Expecting a guaranteed outcome of marital satisfaction from marital treatment is an unrealistic notion.

tary well enough to know what he/ she cannot help with and to make recommendations and referrals when appropriate.

#### What Not to Expect

Expecting a guaranteed outcame of marital satisfaction from marital treatment is an unrealistic notion. Marital treatment is not magic. There is na balm ta fix a bruised or braken marriage. There are no magic wands ta make it all better. Probably the mast comman unrealistic attitude brought into marital therapy is the passive attitude that "now that we are in therapy the relationship will wark." A marriage warks when the husband and wife communicate and negotiate the problems that arise in daily living in the cantext of caring. Therapy works the same way.

A secand false expectation is the notion that the purpose of marital theropy is to keep the marriage tagether. This is not true. The therapy is designed to help cauples understand one another, clarify their own needs, wishes, thoughts and feelings, and identify which traits in each other meet their needs and which do not. They must then negotiate. The jab of the competent therapist is to help the cauple with the issues just mentioned, but the marriage belongs to the cauple, and the decision to remain married or to divorce also be-

langs to the couple.

Another camman mistaken expectation, aften hidden at first, is the idea that the therapist will quickly see that the "prablem is really that the other spause is at fault" and that the therapist will af course help the "well" spouse ta straighten out the "sick" one. If the therapist is inexperienced and believes this notion, the "well" spouse will seem to improve but the marriage will nat. Marriages are camplicated and it takes two ta make the relapionship what it is. One is never salely to blame for the dissatisfactions. The experienced therapist will insist the couple shore the responsibility for sarting out the dissatisfaction.

Faurth, "If we wark hard things will be cleared up quickly." This is rarely true except at the autset. Often things will seem better in the early weeks ar months of treatment. This period is referred to as the "honeymaon" period. However, if lang term change is to take place, feelings of dissatisfaction, hurt, anger and misunderstanding must be explored and worked through. This takes time, and sometimes things worsen befare they get better. A premature decision to end treatment in the "honeymoon periad" will undermine treatment. Ending therapy in a "good mament" may be based an a need to avoid the real issues that trauble the marriage. Additionally, leaving treatment early can only prolang the misery in a traubled marriage.

Fifth, when couples wait until the marriage is dead before caming into therapy they cannot realistically expect the therapist to salvage the relatianship; indeed, they must do the salvaging with help fram the therapist. Unfortunately cauples in very disturbed relationships too aften wait until the partners are sa weary and the injury to the relationship sa great that little treatment is possible. Under these circumstances there is scant reason to attempt treatment. The experienced therapist, after establishing the absence of motivation and the presence of emotional divorce,

### When a marriage is not working some general signs may be evident.

can reflect this observation back to the couple and consider, with them, working toward amicable separation.

#### How Do You Know When Your Marriage Is Not Working?

When a marriage is not working some general signs may be evident. I will describe some signs I have observed, in addition to those described by Joel Block, Ph.D., in his excellent book, The Other Man, The Other Woman.

- 1. When you find you are more content to be alone rather than in the company of your spouse, not sometimes, but most of the time.
- 2. When you prefer the company of someone other than your spouse most of the time.
- When you believe your spouse is harmful to your children or that they would be better off without him or her.
- 4. When the feeling of the marriage is heavy and serious most of the time: all the fun is gone out of it or was never there.
- 5. When you dread coming home at night; when working feels more comfortable.
- 6. When you associate your relationship with your spouse with painful experience.
- 7. When your most constant feeling about your spouse is anger.
- 8. When your attachment to your child is stronger than your ottachment to your spouse.

Let us now consider some of the common danger signals that can alert a couple that they are in difficulty and need professional help.

1. Frequent, unresolvable arguments in which one or both spouses are left feeling angry, hurt, and re-

sentful. These unresolved arguments and the feelings they create tend to be stored up to come out later in painful ways.

- The suspicion or discovery of an extramarital affair. Affairs are a signal things are not going well, that needs are being met outside the marriage.
- 3. Repetitive arguments over what appear to be insignificant issues. Some of these arguments may serve the purpose of getting "distance" from one another.
- 4. Arguments about the children or finances that are really marital issues being fought out in other arenas. This is a way to avoid the "real," more painful issues.
- 5. Feeling of being "outside," ignored or unwanted by the family: "she only wants me for my poycheck; he only wants a mother, maid or sexual outlet."
- 6. Frequent avoidance of intimate sharing with each other. There are many ways people living together can avoid being alone with each other. Some couples arrange to have other people around all the time frequent house guests, friends for dinner, friends to share vacations, to spend weekends with filling the time with people to buffer the marital relationship. Children are used for this purpose as well. Different working shifts, different bedtimes and arguments at bedtime to avoid sexual confrontation are also examples.
- 7. Over-dependence on the part of one or both partners. This can be seen in constant checking up on each other, in not feeling comfortable and worthwhile without a spouse's constant companionship, in resentment of a spouse's separate interests, in living in the shadow of a spouse's achievements and in being easily

wounded by a spouse's criticisms.

- 8. Complaints of sexual incompatibility. This includes complaints from either partner about their sexual relationship and includes lack of attraction to or arousal of one's spouse; complaints about the ability to attain orgasm if it is desired; differences in desired frequency of intercourse; and the lack of warmth, tenderness and mutual pleasure.
- 9. Compulsive extramarital relationships. These are different from a long standing "love affoir." The compulsive liaison is not the same in intensity of involvement or threat to the marriage as is the longstanding love affair outside the marriage. The compulsive affair is motivated by hostility, revenge and dependency. Both types need to be addressed in treatment.
- 10. Marital neglect. A spouse may be so overinvolved in work or avocational pursuits that, by virtue of the time spent, the morriage and family are put too low on the priority list to sustain an important relationship. A spouse who is overinvolved in the children to the exclusion of the marital relationship is neglecting the marriage.

#### How to Choose a Therapist

Therapists come in many shapes and sizes with different qualifications and training. Let's take a look at some of the therapists you might find in your community.

The Social Worker. The minimum standard for a professional social worker is a Master's degree in social work (M.S.W.) earned by attending an accredited graduate school of social work. There is national certification by the Academy of Social Work, as well as local, state and national organizations that enforce profes-

## Therapists come in many shapes and sizes with different qualifications and training.

sional stondards of practice. In seeking to undertake morital work with a social worker, a couple should ask about specific training in marital and family theropy including training and supervision by a competent marital theropist. It is not so much the professional label as the specific training and personal qualities of the therapist that are important.

The Psychologist. The psychologist is an individual with a doctoral degree from an accredited university or professional school. Beyond the degree, appropriate registration, certification ond/or licensing should have been obtoined. Because psychologists do not have a degree in medicine they connot prescribe medications. If medications are needed they will refer the patient to a psychiatrist or medical doctor. The training of psychologists varies. They may, or moy not, have special troining in marital and family therapy. It is appropriate to inquire about such training.

The Psychiatrist. Psychiatrists are medical doctors with a license to practice medicine. In addition they have taken four years of speciality training in psychiatry that may, or may not, include the specific study of marriage and family. Some states ollow physicions who have not token any special psychiatry training to call themselves psychiatrists. Again, it is important for the individual seeking a therapist to interview the therapist

regarding specific training. The physician may hove completed the requirements of the American Board of Psychiatry and be board certified to proctice psychiatry. This certainly suggests competency in the management of psychotropic medications but does not answer the question regarding training in morital work.

The Marital and Family Therapist. This is a relatively new category of care givers. In the state of North Corolina House Bill 1134 (1979) established an act requiring certification of certain individuals who use the title "Certified Marriage and Family Counselor/Therapist" and created the State Boord of Morital and Family Therapy Examiners. This bill declares marital and family therapy in the state of North Carolina to be a professional practice which affects the public safety and requires appropriate certification and control to ensure that the public has a means of protecting itself from improper, unqualified use of certain titles by persons who practice marital and family therapy. The minimum standard for certification is a Moster's degree in clinical social work, Master's in psychiatric nursing, Doctor of Medicine or Doctor of Osteopathy degree with an appropriate residency training in psychiatry; or Moster's degree in any mental health field wherein the course of study is equivalent to the Master's degree in marital and family therapy. The degrees must be granted by

on accredited educational institution. In addition to the educational requirements, at least 1,500 hours of clinical experience in the proctice of marital and family therapy must be completed, 1,000 hours of which must be obtoined subsequent to the granting of the degree and with the ongoing supervision of a qualified supervisor. The condidate for certification must also pass the state examination. The North Carolina State Board of Maritol and Fomily Therapy Examiners is located at the Bowman Gray School of Medicine, Marital Health Clinic, in Winston-Salem. There is also a professional American Association of Maritol and Family Therapists in Washington, D.C., founded in 1942 for the purpose of defining and implementing high standards of education and practice for the field of morital and family theropy.

Choosing a marital theropist is often difficult. Recommendations from friends, fomily, physicions and lawyers are sometimes useful, sometimes not. It is sofer to choose o therapist who has had reputable training and experience. (Even the "best" therapist is bound to have bad days.) Well trained and experienced therapists ore certain to do better with some couples than others. The most important consideration, in my opinion, in addition to education and training, is your judgment. The most effective way to make the decision is

It is safer to choose a therapist who has had reputable training and experience.

## The length and cost of treatment need to be addressed. . . . The range of professional fees is broad. . . .

to occept referrols from professional ossociations, friends and other professionals, and then to shop oround. This may prove to be expensive; however, in the long run you may sove time and money by establishing o compotible fit with a therapist. Given an opportunity to experience the therapist's style and personality is helpful. It is important to experience your own level of comfort and to see if what the therapist says makes sense to you. Do you feel understood by the theropist? Do you feel hopeful after seeing the therapist? These are important questions to answer as you decide whether you want to work with a particular practitioner.

The length and cost of treatment need to be addressed. For many couples the most important consideration is sometimes the cost. The range of professional fees is broad and can be influenced by the education and training of the therapist. The fee range may go from \$30 to \$80 or more per hour. The treatment hour can run from 50 to 60 minutes. Community agencies and clinics both public and private usually offer lower fees and sometimes have sliding scales based on income. Often the fees are higher at a major medical center than in the community of lorge. Insurance reimbursement is an important issue to discuss with the theropist. You should know ahead of time what your particular coverage is for outpatient psychiatric treatment.

Many componies disallow marital treatment. If your policy does not cover morital treatment you need to toke that into consideration before you enter treatment. It is not easy to become involved in treatment with a theropist whose fees you will not be oble to afford on a weekly basis.

The length of treatment also varies. This depends upon the nature of the marital complaint and the flexibility of the partners. On the bosis of the diagnostic evaluation (usually the first three hours), the therapist should tell you what he thinks and moke recommendations for treatment, including the probable length of treatment. Although it is not possible to know ahead of time, it is usually possible to speculate if the treatment will be long or short term. If the moritol difficulties ore quite serious treatment is likely to be once a week for up to three years. As progress is made, treatment frequency can be decreosed. Sometimes progress is made quickly and what oppeared to be long term treatment con become shorter. Treatment under a vear is considered short term. Some therapists may contract to work toward o well-defined goal within a specific number of sessions. Some will insist the treatment is over at the end of the ogreed time. Other therapists will work within blocks of time with the option to stop, evoluote, and opt to extend the time. Still other therapists will work in the open-ended model

looking toward long-term treatment. Regardless of the duration of treatment it is doubtful that progress will proceed in an orderly fashion. Gains tend to be made and lost and made again. Periods of "backsliding" and getting stuck are to be expected in even the most successful therapy.

Finally it is important to take a look at satisfaction with treatment. This is an often neglected aspect of treatment. Outcome studies on satisfaction with the treatment need to be done. In my own practice, part of the termination process is the patient's evoluation of the therapist and o hard look at the original goals and final results as experienced and defined by the patient.

An informal survey among my marital and family therapist colleagues revealed satisfaction estimates ranging from 50 to 90 percent. Some interesting thoughts about this range of satisfaction were expressed. First, the chronicity of the marital distress emerged as an important variable. The longer the problem within the marriage the more difficult the treatment due to the normal resistances to change.

Second, the method of entry into the health care system is important. Marital and family cases referred by the court for child abuse, spouse abuse and sexual offenses are, in general, cases that therapists and patients report low in satisfaction regarding process and outcome. Coses

The longer the problem within the marriage the more difficult the treatment.

that are referred by the court, "made ta go into treatment" by other professionals or others they are dependent upon, are less likely to find treatment of value.

Motivation remains one of the most important variables affecting satisfaction with outcome.

Lastly I would add, in addition to wanting treatment, the couple must be (sufficiently) psychologically-healthy to tolerate the intensity of feelings that are stirred up in the ther-

ару.

I think an experienced therapist, who is able to select cases carefully, will have satisfied patients 90 percent of the time. There are always clients who will come to treatment in order to "prove" the marriage is unworkable, the therapist incompetent, the spouse crazy and thus divorce the anly viable aption. This autome could also be seen as satisfactory depending on your perspective.

In brief summory, the question

"why marital therapy?" is an important one. The answer is a personal one, individual to each of us. As a practitioner for ten years it seems to me that when a marriage or family is in pain it makes sense to understand the possible causes of the pain, consider the options available and make decisions in the most informed way we can. In some cases a professional therapist can help in this process.

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#### **Abortion**

#### Assad Meymandi, M.D.

The number of words written about abortion in recent years, by pro-lifers and pro-choicers, will indeed fill the halls of the Acropolis. Aesculapius, the mythical Greek god of healing, would probably have no time nor ony interest in this body of literature, since it reveals so little. Attempting to make some sense out of this literary chaos since 1973, when the United States Supreme Court legalized abortion, I have found a few pieces of genuine and unselfish work that offer some hope.

The key issue is a simple one: To avoid abortion, we must prevent unwanted pregnancy. First, there is the Alan Guttmacher Institute, which offers dispassionate factual information on a regular bosis. In their latest publication, March 1985, they indicote that the United Stotes is the only developed country where teenage pregnancy is on the rise. We had over one million in 1984. The report shows that the lowest rate of teenage pregnancy and abortion occurs in those developed nations that have liberal attitudes towards sex, where contraceptives ore easily obtained by teenagers and where there are effective sex education programs.

A research program — Project Redirection — recently compiled dato demonstrating that girls and young women from New York, Boston, Phoenix and Riverside, Colifornia who were given wide ranging assistance, which included access to contraceptives, counseling in school and job support, had a much lower rate of pregnancy. This unpretentious project, manned and directed by genuinely concerned individuals and not social do-gooders or the federol gov-

ernment, eloquently demonstrated the effect of community involvement in reducing the incidence of teenage pregnoncy. The impact of the work of this relotively unknown group was further enhanced by a report from the Manpower Demonstration Research Corporation, which had originally supervised the experiment, that one year after the program's end almost half the participants become pregnant and 40% were neither in school nor employed. Therefore the need for sustained guidance and involvement became obvious and necessory.

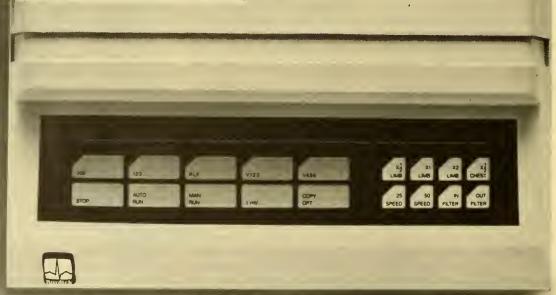
Another small project, the Saint Paul Maternal and Infant Care Project, has demonstrated that it can reduce the rate of pregnancy amongst teenage clients.

These small projects have impressed the Select Committee on Children, Youth and Families, headed by Representative George Miller, a California Democrat, Miller's committee has been holding hearings since Morch 1985. Thirty million dollars has been allocated in devising systems of planned parenthood and in dealing with obortion on a preventive basis, namely educating teenagers. The circulated proposal from the Congress calls for in-school clinics which would provide health services, employment counseling, education in being a parent, and childcare to enable adolescent parents to complete school. The proposal would facilitate providing contraceptives to local communities. In the heat of the budget debate, Title X of the Public Health Service Act was re-authorized by a congressional committee with bipartisan support. This, too, will help finance counseling and education in schools. According to the National Family Planning and Reproductive Health Association, a non-profit ossociation representing 4000 clinics receiving federol money, this is a good sign. A reasonable approach to the problem of abortion is to prevent it from happening. This cannot be done by federal, stote or local governments. Parents, families and churches should be responsible to spread the gospel of sexual responsibility.

In my opinion, an ideal solution to our present dilemmo is for the PTAs throughout our state to declare teenage pregnancy and abortion as a mojor public health problem. Pregnancy connot be prevented with vaccine. However, it can be prevented through education. We must provide cooperation between parents, teochers and clergy to develop a reasonable and socio-medically sound curriculum of sex education for our youngsters. In those communities in states such as Utah, where church activities are an integral port of school and family upbringing, teenage pregnancy is almost nonexistent. It seems reasonable for our religious institutions and churches to transform themselves from ghettos of indifference to involved and pulsating participants in providing necessory sex and health education to our children. After all, churches are made of people who either have children or are ex-children! The only hope for solution of the problem of obortion is not legislation, oratorical rhetoric. emotionalism, unreosonable rotionalism, name-calling, and pontificating wrathful denunciation of those who disagree, but cooperation and development of sound and reasonable educational tools. Abortion is a cruel, if not barboric, form of contraception.

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## Weiss V. York Hosp.: The Separate Medical Staff and the Antitrust Bogeyman

William L. Trombetta, J.D., Ph.D.

This article addresses the problems physicians may encounter as they
attempt to organize themselves into a workable unit in an increasingly
complex health care marketplace.

RECENTLY, a dispute over the merits of separate medical staff legal representation has arisen within a larger context of turmoil and change in the delivery of health care and access to key delivery channels in the health care network.

One school of thought asserts that disaster awaits those who cloak themselves in separate legal entities because their exposure to antitrust conspiracy potential is increased. On the other hand, certain commentators suggest that such fears are blown out of proportion because mere separability, in and of itself, cannot lead to increased antitrust vulnerability. This sharp disparity in perspective, depending on whose side the advocate is affiliated with (the hospital's or the doctors'), makes it imperative to determine what constitutes a conspiracy when independent competing providers make decisions that affect intra staff and inter-provider competition.

The appearance of a rash of recent lawsuits involving medical staff privileges and access to hospital facilities has caused courts to initiate a fundamental reexamination of the essence of the medical staff and its relationships with various constituencies, including relationships among members of the medical staff itself.

It is arguable that all members of a separate organized medical staff will not be liable for antitrust violations stemming from direct anticompetitive conduct of only a few staff members. For example, if the medical staff were organized as a corporation, the staff would most likely be at risk for no more than the assets of the corporation while physicians, simply because they are members (apart from those directly involved in anticompetitive conduct), cannot be held liable for any judgments assessed against the corporate defendant, the medical staff.3 Unfortunately, while this development may chill volunteer and altruistic efforts (as is apparently the case with increasing reluctance of people to serve on Boards of Directors for any organization due to unforeseeable liability exposure) on the part of well meaning physicians who might heretofore have taken on such potentially litigable efforts, it should not result in increased antitrust exposure. Physicians with staff privileges may think twice before committing themselves to serve on medical staff committees that directly involve them in staff privileges applications, termination and appeals processes.

The Third Circuit's recent opinion in Weiss v. York Hosp.<sup>4</sup> attempts to deal with the hospital/staff/conspiracy dilemma. The court focused on the numerosity requirement for a conspiracy under Section 1 of the Sherman Act. To have a conspiracy under antitrust law, more than one person must be involved. The Weiss Court concluded that a hospital and its medical staff are incapable of conspiring with each other. In addition, the court held that the York Hospital medical staff constituted "a combination of individual doctors" and, as a result, the actions of the staff satisfied the numerosity requirement of Section 1 of the Sherman Act. The court remanded for reconsideration of the scope of the trial court's injunction against York Hospital and its staff.

The severity with which the conduct at issue in *Weiss* was viewed is reflected in the appellate court's application of the harsh per se standard to a concerted refusal to deal. Typically, and certainly more recently than before within a professional context, the courts lean toward applying a less stringent standard to what is normally regarded as a heinous form of anticompetitive conduct — concerted refusal to deal or, as it is also known, group boycott. A group boycott involves two or more persons conspiring for the purpose of excluding or not dealing with a particular competitor or a particular kind or class of competitor. Prior to this decision, the conventional wisdom would have predicted that anything short of horizontal price fixing would have resulted in the more defendant-oriented rule of reason standard.

Hence a most important premise at the outset is to position oneself so that any challenge is evaluated under the "rule of reason" standard, not the "per se" standard. As draconian as the per se standard is for defendants, the "rule of reason" is equally devastating to a plaintiff because under this standard the plaintiff has the burden to prove that the conduct at issue (e.g., termination of or exclusion of staff privileges) is more anticompetitive than procompetitive. Even if the challenged conduct is merely competitively neutral, the plaintiff still loses. Hence, the moral is that the more one can document and substantiate (and the more quantitative and empirical such a record is, the better) that what you are doing is more procompetitive than anticom-

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petitive, the more difficult it is for the plaintiff to prove his case. Under the per se standard, all the plaintiff has to do is establish that the conduct took place; he doesn't have to say anything about the impact on competition. He doesn't even have to prove what the relevant "product" and geographic markets are. Under the rule of reason, such proof is a threshold requirement. Therefore, this premise is extremely important because the rule of reason places a very heavy burden on a plaintiff.

The Weiss Court found that different standards were applied to prospective osteopaths and M.D.s. Even hearsay could be relied on to reject a D.O., but not an M.D.<sup>5</sup> Moreover, upon admission D.O.s were, in effect, second class citizens. The evidence at trial indicated that M.D.s and York Hospital combined in an unlawful conspiracy to exclude osteopaths from the medical staff.<sup>6</sup>

Curiously, the Weiss Court of appeal did not raise the similarity of the interests at issue in Weiss as analogous to trade association cases that also involved anticompetitive conduct. For example, in Robinson v. Magovern,7 a staff privileges/antitrust case, that court discussed the unsuccessful plaintiff's group boycott claim; that is, that the defendants allegedly conspired with each other to exclude Dr. Robinson from the hospital's medical staff. The Robinson Court cited a 1961 trade association case<sup>8</sup> for the finding that the defendants in Robinson did use objective standards in evaluating and rejecting Dr. Robinson's application and that, notwithstanding the fact that competitors of Dr. Robinson were in a position to influence the decision on his application, the input on his application process was provided unilaterally and independently. In other words, there was no basis for finding a conspiracy to keep Dr. Robinson off the medical staff.

The similarity between the trade association and staff privileges settings is striking. Both situations involve competitors in a position to influence a decision that could adversely affect at least potential competitors, if not the competitive process itself. <sup>10</sup> Not only is the similarity there but also there is an important implication for the extent of liability that can attach to the organization and its members.

For example, in another trade association case, 11 the Supreme Court recently held that a nonprofit, standardsetting engineering association (as in the Radiant Burners case) was liable for the antitrust violations of agents acting within the scope of their apparent authority. While the principles of agency law are beyond the scope of this article, the relevant point is that the trade association operated in *corporate* form with over 90,000 members drawn from all areas of mechanical engineering. Volunteers from industry and government did much of the work in promulgating codes and regulations. The trade association was held liable as a corporate entity for the anticompetitive conduct of its agents but each and every member of the organization was not found liable. 12 Again, while the Hydrolevel decision, and others like it (including Weiss v. York Hosp.) may well dampen one's enthusiasm for volunteering to serve on committees that affect substantial constitutional, commercial and property interests, the matter of the form of doing business is irrelevant from an antitrust perspective.

A case that did play a prominent role in Weiss v. York

Hosp. is the Supreme Court's recent June, 1984 Copperweld Corp. v. Independence Tube Corp. decision. <sup>13</sup> The court overturned what came to be known as "the intraenterprise" or "bathtub conspiracy" doctrine. <sup>14</sup> Basically, that doctrine held that a parent company and its subsidiary corporation, even though there was common ownership, were still capable of conspiring with each other for purposes of satisfying the "conspiracy, combination, contract" requirement of Section 1 of the Sherman Act. The Copperweld Court overturned the outdated intraenterprise doctrine stating that a parent company and its wholly owned subsidiary always have a "complete unity of interest." <sup>15</sup> Chief Justice Burger went on to declare:

Especially in view of the increasing complexity of corporate operations, a business enterprise should be free to structure itself in ways that serve efficiency of control, economy of operations, and other factors dictated by business judgment without increasing its exposure to antitrust liability. <sup>16</sup>

Interestingly, another court came to the same conclusion as the Third Circuit in *Weiss* at about the same time. In *McMorris V. Williamsport Hosp.*, <sup>17</sup> the nuclear medicine department changed to an exclusive contractual arrangement. The plaintiff-physician was forced out and filed suit alleging tying and group boycott (per se unlawful antitrust violations requiring a contract, combination or conspiracy). As did the Third Circuit in *Weiss*, the *McMorris* court relied on *Copperweld* holding that a hospital and its medical staff are incapable of conspiring among themselves. The trial court stated that the staff acted as a unit or arm of the hospital.

The Weiss appellate court found Section 1 liability with respect to the medical staff but not the hospital. If the medical staff is but an arm of the hospital, that is, its agent, it is not clear why the staff's anticompetitive conduct was not imputed to the hospital. For example, under Copperweld, a parent and its subsidiary are incapable of conspiring with each other. Yet, if a subsidiary of a corporation engaged in price fixing with a competitor, its unlawful conduct would be imputed to the corporation parent.

The appellate court in Weiss reasoned that although the individual physician staff members had independent economic interests in competing with each other, the staff as a whole was not in competition with the hospital. Still, this leaves unanswered the question why the staff's conduct did not result in liability for the hospital as did the trade association members' conduct in Hydrolevel or as would anticompetitive conduct on the part of a corporation's subsidiary.

But the Third Circuit did not say that any particular form of organization, or the mere fact that the individual staff members came together to form an organized entity, necessarily results in antitrust exposure. In other words, any medical staff can be characterized as a generic entity that exists as an entity regardless of whether it is separately incorporated or not. In fact, the medical staff at York Hospital was not separately incorporated and antitrust liability was still found.

The Weiss Court described the York medical staff as "a group of doctors, all of whom practice medicine in their individual capacities, and each of whom is an independent

economic entity in competition with other doctors in the York medical community. Each staff member, therefore, has an economic interest separate from and in many cases in competition with the interests of other medical staff members." Hence, by its very nature, individual physicians of a medical staff inherently satisfy the numerosity requirement as a group entity regardless of what form (or non-formal association) or organization the individuals select.

Although the Weiss Court acknowledged that the York medical staff is a separate economic entity and, therefore, more than simply an association of doctors, the question of who does or does not get access to hospital staff privileges has to be determined by the "medical staff" in general and direct participants in the application process regardless of whether or not the medical staff is incorporated. 19

As further evidence of the irrelevance of separate incorporation, note the language used by the Third Circuit in characterizing the discriminatory standards for staff privileges between M.D.s and D.O.s as to whether the per se or the rule of reason standard would be applied: "In this case, because of the M.D.'s control over York's admission decisions, ... "20 The appellate court does not even bother to use the term, "medical staff." The economic reality is that individual physicians control hospital staff privileges; the fact that a medical staff may incorporate to operate as a separate economic entity in order to provide services separate from those provided by the doctors on the staff<sup>21</sup> should not add to or detract from the "substance" of the arrangement<sup>22</sup> for the purpose of antitrust law.

#### Conclusion

The Third Circuit's opinion in Weiss v. York Hospital raises at least two significant concerns. First, although a kind of "strict liability" by virtue of association with a particular form of doing business is not intended by the court (nor suggested by legal precedent) it is not clear whether all members of a medical staff, even those with no direct involvement in the staff privileges application process, are or can be found liable for anticompetitive conduct of the medical staff as a recognized group entity.

Also, it is not clear why the defendant York Hospital was not found liable given the Third Circuit's principal/agent language, which precluded a conspiracy between the hospital and its staff but should not have exonerated the hospital from the unlawful conduct of its "multiple team of horses,"23 namely, the medical staff.

It is submitted that physicians who have gained hospital staff privileges as providers and/or as participants in the staff privileges access application or review process are inevitably caught up in a tension between the legitimate needs of the hospital and their own economic self interest. Physicians may perceive the medical staff as a logical vehicle for organizing as a separate economic entity to enhance their ability in competing with hospitals that choose to compete with their own medical staffs by unbundling selected outpatient services. On a more positive note, a separate medical staff corporation can not only facilitate hospital-medical staff cooperative joint ventures but also provide physicians with a collective economic entity that can interface with business coalitions and third party payors in efforts to provide quality health care at reasonable cost.

As the United States Supreme Court stated in Copperweld, 24 in an increasingly complex health care market place, the form in which one chooses to do business should not increase antitrust liability. Surely, if medical staff participants are acting anticompetitively to restrain trade, the economic substance of such conduct can be attacked directly without suppressing the desirable procompetitive benefits that flow from a mere form of doing business. The fact that a medical staff has chosen to take on a separate economic identity does not affect the economic self interest of individual physicians. The ability of medical staff participants to restrain trade is not any greater simply because the physicians formalized an arrangement that is inherently group conduct to begin with.

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- 4 Weiss v York Hosp., Nos. 82-3507, -3580, -3581 (September 27, 1984) (Slip Opinion).
- 5. Id. at pp. 12, 13.
- 6. For a comprehendable overview of the trial court opinion and the underlying facts and background leading to the lawsuit, see Medical Economics, pp 230-238 (August 6, 1984); Weiss v. York Hosp., 548 F. Supp. 1048 (M.D. Pa.
- 7. 521 F. Supp 842 (W.O Pa. 1981).
- 8. Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S 656 (1961).
- Robinson v. Magovern, supra, at p. 908.
- 10. The antitrust laws are concerned with protecting competition, not competitors. Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477 (1977)
- 11. American Society of Mechanical Engineers, Inc. v. Hydrolevel Corp., 456 U.S.
- 12 Ironically, but for state law claims alleging tortious interference with contractual relations, no individual defendants were found liable for violating Section One of the Sherman Act in Weiss v. York Hosp.
- 13 104 S. Ct. 2731 (1984).
- 14 United States v. Yellow Cab Co., 332 U.S. 218 (1947).
- 15. Id. at p. 2742 and quoted at pp. 58-59 n. 48 of Weiss v. York Hosp., Nos. 82-3507, -3580, -3581 (September 27, 1984) (Slip Opinion).
- 16. Id. at p. 2742.
- 17. 1984-2 Trade Cases (CCH) Par. 66, 252 (M D. Pa. 1984)
- 18 Weiss, supra, at pp. 58, 59 19 Weiss, supra, at pp. 59, 60 n. 49
- 20. Weiss, supra, at p 69 (emphasis added).
- 21. Id. at p. 60 n. 49.
- 22. Id. at p. 58.
- 23 Weiss, supra, at pp. 58, 59 n 48
- 24 Copperweld, supra, at p. 2742.

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## The Hen's Egg Versus the Horse's Brain: How Equine Encephalomyelitis Vaccine Established the Dorothy and Joseph Beard Foundation

Will C. Sealy, M.D.

 A fatal equine illness and a shortage of research funds combined to spur the development of a vaccine and the establishment of an endowment at Duke in the 1930s.

THE proof that one hen's egg could produce more equine encephalomyelitis virus vaccine than one horse's brain was of such economic significance that enough funds were accumulated from the sale of the vaccine to establish the Dorothy and Joseph Beard Foundation. The story of how this interesting fact was discovered and the fund launched began with Joe Beard's arrival at Duke University. It illustrates many of the characteristics of this man that made him unique among his university colleagues. It was my good luck to have played a part in this story and my privilege to have enjoyed a long friendship with Joe Beard. These are my reasons for recording these happenings.

According to a conversation with Dorothy Beard a few months before her death, Joe found his place at Duke in this way: She and Joe came to Duke in 1936 with friends from the Rockefeller Institute, the latter attending an anatomy conference. The Beards came as visitors to see their many Vanderbilt friends on the Duke faculty. Among those friends was Paul Sanger, a Senior Resident in surgery, who knew that Dr. Deryl Hart, Professor of Surgery, was searching for a Director of Surgical Research. Paul introduced Joe to Dr. Hart. Joe Beard had finished a surgical residency at Vanderbilt, where he had worked in the laboratory of Dr. Alfred Blalock. He had then joined the Rockefeller Institute in New York as an assistant to Dr. Peyton Rous working with viruses that caused neoplasms. Joe Beard was just the person Dr. Hart was looking for. He was hired.

My introduction to Joe was on his first day at Duke, July 1, 1937. I was the first Surgical Resident assigned to the rotation in the new surgical laboratory. Having expected to do experiments on dogs that required great surgical skill, I was taken aback when I found that the new laboratory's work was to be in virology. Even though my work was to be

on the Shope papilloma virus, the latter was, after all, a rabbit disease. However, my interest and enthusiasm for research were aroused as I became more closely associated with this unusual man.

The first problem that Joe Beard faced at Duke was getting a working laboratory and adequate animal quarters established. This was the first sign to me that Joe was a versatile man. I found he could tear down and build walls; compound dog food from horse meat, black-eyed peas, cod liver oil and brewer's yeast; and make a mouse cage. These various activities were carried out at a feverish pace. Finally, with the animal quarters satisfactory and the laboratory working, my experiments with the rabbit papilloma began but soon were interrupted by a new series of virus studies that were far removed from my concept of surgical research. All our efforts now were directed toward studies on equine encephalomyelitis virus.

Then, as now, research was plagued by a shortage of funds.

As the story was told to me, Joe Beard's laboratory was funded through a \$2,500.00 grant from Mr. Bell, then President of the American Cyanamid Corporation. This amount, incidentally, was slightly less than Dr. Beard's reported yearly salary. The funds were soon exhausted by the purchase of much-needed equipment and other sources of funds had to be found. Joe knew that the vaccine to protect horses against equine encephalomyelitis virus was expensive because the source of the virus for making the vaccine was the brains of infected horses. He decided that he could obtain equine encephalomyelitis virus in large amounts by infecting chicken egg embryos. From this, he could make a much cheaper vaccine and protect horses from this usually fatal illness.

In the experiments, <sup>1, 2</sup> the Eastern strain of equine encephalomyelitis virus was grown in the chick embryo and harvested by grinding the embryo and then centrifuging the mixture. The yields were estimated by titration in mice as

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well as with the ultracentrifuge. In addition, the virus and vaccine could be characterized using the ultracentrifuge. The yield of equine encephalomyelitis virus from one chick embryo, much to our surprise, was equal to or greater than that obtained from one horse's brain. The virus was killed by formalin, resulting in a vaccine which was proven effective by tests on guinea pigs.

As a substitute for the horse's brain, the egg-grown vaccine promised to be very profitable. A patent for the method was sought. A license was given to Lederle Laboratories to make and sell the vaccine. Every horse in the Western hemisphere needed two injections per year at fifty cents per injection. The Western equine encephalomyelitis virus vaccine could be made in this same way.

The next part of this story relates how Lederle Laboratories' personnel were taught to make the vaccine by Joe, Dorothy and me. The pleasant part was the trip to Pearl River, New York, the home of Lederle Laboratories. On the way back to Durham, we visited the Rockefeller Institute in New York. Among the highlights for me was the opportunity to visit the Tissue Culture Laboratory of Dr. Alexis Carrel. Dorothy Beard had been a technician in that laboratory during Joe's tenure at the Rockefeller Institute. The next stop was at the Princeton Branch of Rockefeller Institute to discuss our work with Dr. Ralph W. G. Wyckoff, who shortly thereafter started to work for Lederle Laboratories.

Before coming to Duke, Joe Beard had worked with Dr. Wyckoff in purifying and characterizing the Shope papilloma virus with an ultracentrifuge, an exciting new biophysical tool. From plans furnished by Dr. Wyckoff, Joe Beard and George Newton of Durham, who worked in the Duke Physics shop, made an ultracentrifuge from "scratch" including the analytical part. The instrument was placed in a large laboratory on the fourth floor of the medical school facing the Duke University quadrangle. I used to have the terrible thought, while watching it from the

safety of a sandbag wall, that the head would break loose from its piano wire tether and sail across the quadrangle to the Chapel tower.

The only sad part of what was otherwise a delightful episode occurred in the Summer and Fall of 1938. At the time the work with the vaccine was started, it was not thought that man was susceptible to equine encephalomyelitis. However, in 1938 reports appeared showing that indeed man was susceptible, 3, 4 and the Eastern strain of equine encephalomyelitis was isolated from a child's brain. 5 Some of the employees at Lederle developed encephalomyelitis from making the vaccine and one death was reported. None of the five or six people who worked with the virus at Duke had problems.

This story is really an account of the great versatility, the brilliance and the enormous drive of what I believe to be the person nearest to a genius I met on the Duke faculty. Perhaps I am biased, for my debt to him is great. He introduced me to the laboratory, encouraged me to continue to work, and furnished me with space and animals both during and after my resident years for work on my own. He had strong convictions and was a tough man. He was accomplished and proficient in many things. Among those, in addition to being a versatile and imaginative scientist, were carpentry, cabinet-making, masonry, dairy farming and foreign languages. His influence and guidance of the medical school in the years that Duke emerged as a great research center were enormous.

The new vaccine for horses proved to be successful. The patent with its royalties held for over two years. Enough money, I was told \$50,000.00 or so, came to Duke, and thus the Dorothy and Joe Beard Foundation was funded.

The hen's egg did supplant the horse's brain in making equine encephalomyelitis vaccine and, in so doing, helped launch one of the most productive laboratories in the Duke University Medical Center.

## The Need for Improved Emergency Medical Services in Pitt County

Richard C. Hunt, M.D., E. Jackson Allison, Jr., M.D./MPH and Jesse G. Yates, Ill, EMT-P

 Pitt County's medical community supports considerably upgraded emergency services for their area.

REMARKABLE improvements in the delivery of prehospital emergency medical care have evolved over
the past 15 years. Prior to the development of and federal
mandate for emergency medical services (EMS) systems,
funeral directors with little or no training in first aid often
provided emergency care to victims of accidents; this presented the funeral directors with an inherent conflict of
interest. Many areas of the country are now served by
effective EMS systems with efficient dispatching, rapid
response times, well-trained personnel, effective cardiopulmonary resuscitation (CPR), rapid defibrillation and
advanced life support in the field, including endotracheal
intubation and cardiac pharmacotherapy.

The purpose of this paper is to describe the current status of EMS in Pitt County, North Carolina, and compare it with other types of EMS systems throughout the nation. EMS systems are expensive and, in the era of cost justification, clinicians and EMS administrators have been asked to evaluate whether EMS systems are effective in reducing morbidity and mortality. Put more simply, does the current Pitt County EMS system save lives and, if so, how does it compare with other types of systems in the nation? The specific measure most often used to evaluate effectiveness of EMS systems is resuscitation from cardiac arrest.

#### **Resuscitation Predictors**

Research has documented that survival from prehospital cardiac arrest can be markedly improved when there is a short time from collapse to the initiation of CPR or basic life support ( $\leq 4$  min) and a short time from collapse to provision of definitive care by advanced life support ( $\leq 8$  min). The probability of reaching the hospital alive when the time to initiation of CPR is four minutes and the time to defibrillation and advanced life support is eight minutes is predicted to be 48%. When the time to initiation of CPR increases to eight minutes and the time to advanced life support is 30 minutes, the probability of reaching the hospital alive is reduced to 11%.  $^{1/2}$ 

Initiation of CPR by a bystander is associated with substantially improved chances of survival. In Seattle, where over 175,000 residents have been trained in CPR, a oneyear study showed that 43% of patients found in ventricular fibrillation survived to hospital discharge when bystanders initiated CPR. In contrast, only 21% lived when CPR was delayed until fire department personnel arrived at the scene.<sup>3</sup> A similar study in Los Aneles of bystander CPR initiated prior to arrival of paramedics produced a fourfold improvement in survival (from 5 to 22%) when compared with cardiac arrest patients not receiving bystander CPR.<sup>4</sup>

Rapid access to EMS systems, which decreases the time to definitive care, is expedited by public awareness. A study from Boston in 1984 showed that 75% of the public think they have an EMS system with paramedics when they don't. Furthermore, 79% of the public didn't know their local EMS phone number (personal communication, Charlotte Yeh, M.D.). In many areas of the United States the toll-free number, 911, rapidly accesses police, fire and/or emergency medical services; it is the ideal phone number for an effective EMS system.

The majority of patients who are resuscitated from prehospital cardiac arrest, approximately 68%, are able to resume their previous level of function. Approximately 80-90% are able to achieve independent social living. <sup>2.5</sup> The argument that patients who are resuscitated from prehospital cardiac arrest lead vegetative existences and are thus dependent on society is not valid.

#### **Current Status of Pitt County EMS**

As described above, bystander CPR, which decreases the time to initiation of CPR, is an important component of an effective EMS system. In Pitt County, with a population of approximately 93,000, the American Red Cross taught 54 classes and certified 607 people in 1983, and taught 84 classes, with certification of 1,174 people, in 1984 (personal communication, American Red Cross, Pitt County). Over the past five years the American Heart Association in Pitt County has trained just over 4,000 people in CPR (personal communication, American Heart Association, Pitt County). Using a liberal estimate of 2,000 people trained in CPR in 1984, by combining Red Cross and Heart Association figures, approximately 2% of Pitt County's population was trained in CPR last year. This figure does not exclude the large transient student population from East

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Carolina University or required CPR certification for EMTs and medical students.

A 911 phone number for rapid citizen access to EMS does not exist in Pitt County. The Greenville phone book lists 85 emergency numbers inside the front cover with 17 locations and exchange areas, each with seven different emergency services' phone numbers. "Rescue squad" and "ambulance" are listed separately, but are both shown with symbols of a cross. The service to be called in case of a medical emergency is not identified. The standard symbol for emergency medical services throughout the country is the Star of Life, not the cross shown in the phone book. An interview with a telephone operator revealed that when a caller requests emergency medical care she must in turn dial each individual digit to access an EMS system; there is no direct "hot line" or speed dialing service from the operator to access emergency medical care.

An organized, well-coordinated county EMS system does not exist in the county of Pitt. Prehospital emergency medical care is provided in the city of Greenville by paid EMTs in the Greenville Fire/Rescue Department, and in the remainder of the county by volunteer EMTs who operate "Rescue Squads." It is notable that there are no Pitt County or city of Greenville "Emergency Medical Services." "Fire/Rescue" and "Rescue Squad" are ambiguous names which may confuse and thus delay public access to emergency medical care.

The highest level of training of prehospital emergency medical personnel in Pitt County is at the EMT-Intermediate (EMT-1) level. Most EMT-1s are in the Greenville Fire/Rescue Department. EMT-ls, in addition to providing basic life support for cardiac arrest, are trained to administer IV solutions, obtain blood for laboratory analysis and use the esophageal obturator airway for airway control. They are not trained to defibrillate the heart. Performance of any of the procedures listed above ironically has a negative impact on survival since their execution often means prolonged time spent in the field which ultimately results in delayed access to advanced life support in the emergency department.

Throughout Pitt County there are no paramedics trained to defibrillate and perform advanced life support for prehospital cardiac arrest until the patient arrives in the emergency department at Pitt County Memorial Hospital. In a county with 656 square miles, the detrimental impact of the delayed access to advanced life support is obvious.

In the city of Greenville prior efforts to improve prehospital emergency care have met with little success. A 1981 report by the Committee for Continually Improving Rescue Services to Greenville, NC, noted that on April 10, 1980, a petition of at least 1700 registered city voters requesting autonomous administration for the rescue facility was presented to the city council. No action was taken at that time, and autonomous control of EMS in Greenville does not exist yet. The same report hoped that rescue services would "have great ambition and willingness to assert the extreme amount of effort necessary to advance to . . . paramedical programs. . . . ''6

The current status of EMS in Pitt County is reflected by a 1-2% survival rate for patients of prehospital cardiac arrest taken to Pitt County Memorial Hospital. The inherent prob-

lem with the current system has been documented elsewhere.7 During a two-year period in a system with EMTs limited to basic life support capabilities including defibrillation (EMT-D), 18 (6%) of 321 patients were resuscitated. In comparison, 55 (23%) of 253 patients were discharged in adjacent communities with paramedic services. The evident factor accounting for the difference in survival rates was the time from collapse to receiving defibrillation and advanced cardiac life support - 26 minutes in the EMT-D area compared with 7.8 minutes in the paramedic area.7

Systems using defibrillation (EMT-D) and systems using paramedics (EMT-P) with advanced life support differ from the level of prehospital care in Pitt County in that they offer partial or total advanced life support capabilities.

#### **EMT-D Systems**

Defibrillation is only one aspect of advanced life support, yet its impact alone has a dramatic effect on survival from prehospital cardiac arrest. In a study published in the New England Journal of Medicine in 1980, EMTs in a suburban community of 79,000 were trained to recognize and treat prehospital ventricular fibrillation with up to three defibrillatory shocks without the use of medications or special airway protection. During a two-year period with standard care by EMTs, four of 100 (4%) patients with cardiac arrest were resuscitated and discharged. In comparison, 10 of 54 (19%) cardiac arrest patients in a one-year period where defibrillator trained technicians provided care were discharged alive (p < 0.01).<sup>8</sup>

Systems with EMT-Ds have been shown to improve survival rates in rural communities. EMTs in 18 small communities with an average population of 10,400 were given a 16-hour training course to recognize and defibrillate ventricular fibrillation. In communities where early defibrillation was available, 12 of 64 (19%) who were found in ventricular fibrillation were resuscitated and discharged alive from hospital. In control communities without EMT-Ds, only one out of 31 patients (3%) was discharged alive. The authors concluded that early defibrillation by minimally trained technicians may be an effective approach to emergency cardiac care in rural communities.9

Researchers from Nebraska constructed a model to analyze the difference in expected results from EMT-D systems among communities of varying populations. In urban Nebraska with a mean population of 242,000, EMT defibrillation would occur once every six weeks; in intermediate cities with a mean population of 22,300, EMT defibrillation would occur once per year; and in rural areas with a mean population of 1,500, EMT defibrillation would occur once every 5.6 years. The low frequency predicted for EMT-defibrillation in rural areas such as Pitt County with a population of 93,000 would probably necessitate a strict monthly recertification process. The Nebraska model predicts a relatively low cost per life saved: in urban areas successful EMT defibrillation would cost \$566 per life saved and in rural areas, \$4,785.9. 10

There have been few problems with EMT-D performance. Accidental electrical countershock to EMT-Ds or others has occurred twice in 1500 countershocks (e.g., physical contact with patient during defibrillation). Electrical countershock of patients not in ventricular fibrillation is extremely rare. The two rhythms which are difficult for EMT-Ds to interpret rapidly are ventricular tachycardia and very fine ventricular fibrillation. Electrical shocks to patients when the heart was effectively pumping blood have not occurred. Medical directors of EMS systems may be wary of "trigger happy" defibrillator technicians; however, failure to defibrillate patients who were in ventricular fibrillation and delays in the delivery of countershocks have been persistent problems.<sup>11</sup>

#### Paramedic (EMT-P) Systems

As of 1982 there were greater than 300 paramedic EMS systems in the United States.<sup>2</sup> Time from collapse to advanced life support, one of the important predictors of successful resuscitation, is diminished by paramedic systems bringing advanced life support to the patient.

Researchers do not advocate replacing paramedics with EMT-Ds. Rapid defibrillation by EMTs is designed to treat only one extreme medical emergency and offers little or no benefit for other emergencies such as myocardial infarction with dysrhythmia(s), hypoglycemia or trauma. Furthermore, paramedic systems are the only EMS system configurations with full advanced life support capabilities including endotracheal intubation, defibrillation and drug therapy.

The positive effects of paramedic systems, particularly on outcome of prehospital cardiac arrest, are well-documented. Survival rates defined as admission to the hospital vary between 22% and 65.4%. For patients discharged alive from hospital the rate varies between 3.5% and 31.8%. The wide ranges of success are reflections of different subsets of cardiac arrest patients grouped according to variables such as rhythm, bystander CPR, etc. 12

In Columbus, Ohio, paramedics were compared with physicians' performance. Serial evaluation showed that paramedics in that system perform as effectively as physicians in diagnosing and caring for acute cardiovascular emergencies, including endotracheal intubation. <sup>13, 14</sup>

Estimates of costs and benefits in paramedic systems are difficult. While limited in number, cost benefit analysis of paramedic systems by theoretic and pragmatic studies reveal favorable economic impacts. Since CPR by lay persons coupled with prehospital defibrillation now triples the long-term survival rate, favorable cost-benefit ratios can be effected by adding advanced life support to an extant ambulance system.<sup>15</sup>

Support for paramedics in rural areas, such as Pitt County, comes from a study by Spoor. In a rural system with paramedics it was found that none of the cardiac arrests was successfully resuscitated; however, myocardial infarction patients with dysrhythmias were adequately controlled at the scene. No deaths occurred in this group en route to the hospitals. This category may prove to be the most important group for prehospital intervention in rural cases. <sup>16</sup>

#### What should be done in Pitt County?

The need for improved emergency medical services in Pitt County is clear. Although there are approximately 100 cardiac arrest victims per year in the county of Pitt, review of the last 200 ambulance run sheets and Emergency De-

partment charts reveals a resuscitation rate of 0, compared with the present national survival rate in locations with well-structured systems with advanced life support capabilities of 20 to 25%. <sup>17</sup> The potential for a 20 to 25-fold improvement in survival is significant indeed.

The foundation upon which Pitt County can improve prehospital emergency medical care consists of, first, increasing the participation of bystanders in the resuscitation of cardiac arrest victims through increased CPR training of the general public; second, providing EMTs with the capability for defibrillation in the field; and third, developing a well-structured EMS system. The elements of a successful EMS system are simple but effective — efficient dispatching, rapid response times, well-trained personnel, effective CPR, rapid defibrillation and additional advanced life support in the field. 17 Once available, defibrillation by EMTs will occur most often in and around the city of Greenville because of the population density there approaching 50,000, which will result in approximately 8 to 10 defibrillations per month. While we have mainly addressed the problem of prehospital cardiac arrest, an improved EMS system would result in better prehospital care for other medical and surgical emergencies in Pitt County.

The medical community of Pitt County and its resources are ready to support improvements in the EMS system. In April 1985, the Pitt County Medical Society unanimously passed a resolution to unequivocally support the development of paramedic services in Pitt County. In October 1985, the North Carolina State Board of Medical Examiners passed new rules and regulations establishing a new level of EMT, the EMT-Advanced Intermediate. These persons will serve as "cardiac technicians" who will be able to perform the following life support measures: defibrillation, endotracheal intubation, sodium bicarbonate, epinephrine, atropine, lidocaine, D<sub>50</sub> and naloxone. It is obvious that the incorporation of this degree of advanced life support in the prehospital phase of emergency medicine in the county of Pitt would indeed be a marked improvement over what currently exists. Pitt County Memorial Hospital, East Carolina University School of Medicine, the Division of EMS and the residency training program in emergency medicine within the Department of Emergency Medicine are all resources for training and development of an improved EMS system in Pitt County.

#### Acknowledgment

The authors wish to express their thanks to Rosie Walsh and Doris Vincent for assistance in preparing the manuscript.

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#### Pseudogout in a Patient on Renal Dialysis

G. Wallace Kernodle, Jr., M.D. and Salutario Martinez, M.D.

A N afebrile 32-year-old black man who was on a regular schedule of tri-weekly hemodialysis developed acute inflammation of the dorsal aspect of the second left metacarpophalangeal joint and the tissues between the second and third metacarpals. Any motion of the second finger caused pain.

Bacterial infection, gout and pseudogout were the most likely diagnoses. Aspiration of the joint produced three drops of clear, culture-negative, synovial fluid with normal viscosity. No urate or calcium pyrophosphate dihydrate crystals were seen under the polarizing microscope. X-ray examination revealed soft streaky calcific bands in the second extensor communis tendons, in the medial interossei between extensor communis tendon and in the medial interossei between the second and third metacarpophalangeal joints. His blood calcium was normal but his phosphorus was elevated at 13.5 mg/dl. The diagnosis of calcific periarthritis was established. He was treated with immobilization of the inflammed area, indomethacin and encouragement to comply with his schedule for taking phosphate-binding antacids. Within three days the inflammatory reaction had subsided.

At least three calcium-containing crystals are known to deposit in joints and periarticular structures, mimicking the presentation of acute gout and producing calcification seen on radiographs. 1 Calcium pyrophosphate dihydrate crystal deposition disease, or classic pseudogout, is a common cause of arthritis in the elderly and is diagnosed by the identification of weakly positively birefringent rhomboidal crystals in synovial fluid. Hydroxyapatite crystals may be identified only by electron microscopy and are commonly found in bursitis and periarthritis. Rarely, calcium oxalate deposition, diagnosed by identification of bipyramidal crystals by light microscopy, may cause an acute arthritis or calcific periarthritis. The latter two are noted in renal dialysis patients, possibly because of their high serum phosphates. Therapy consists of joint immobilization, nonsteroidal anti-inflammatory agents, and occasionally local injection with depot corticosteroids.

From the Departments of Medicine and Radiology, Duke University School of Medicine, Durham 27710.

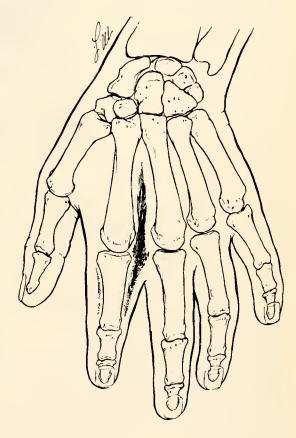


Figure 1. Sketch of left hand oblique view radiograph showing areas of ectopic calcification.

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#### Letters to the Editor

#### Neck Masses

#### To The Editor:

I enjoyed reading the article "Neck Masses — Illustrations of a Logical Approach" by Eugene W. Linfors and Francis A. Neelon which appeared in the November 1985 issue of *The North Carolina Medical Journal* (46:574-8). It is worthy of additional note that the technique of fine needle aspiration biopsy also has significant applications in the evaluation of such masses.

Congratulations on the elegant restructuring of the *Jour-*

William W. Johnston, M.D. Department of Pathology Duke University Medical Center Durham 27710

#### Internecine Battles

#### To The Editor:

I would like to respond to Dr. Dykers' letter in the *North Carolina Medical Journal* of November 1985 (46:621-2). I found his comments about non family practitioners to be beyond the bounds of propriety. His stereotype of internists was melodramatic and unfair. We are just as interested in the best overall data base for our patients as Dr. Dykers is for his patients. Furthermore, it is ironic when he cautions that family physicians should not be guilty of thinking in "pigeon holes." What does he call categorizations of his colleagues in the last two paragraphs of his letter?

I would advise Dr. Dykers to adopt a more harmonious view of his fellow physicians rather than one that is so pernicious (or internecine, as it were).

Jeffrey A. Margolis, M.D. 603 Beaman Street Clinton 28328

#### The Doctor Turns Patient

#### To The Editor:

I enjoyed the recent "Learning Without Words" article that appeared in the November 1985 North Carolina Medical Journal (46:565-6). Both patients have pigment abnormalities. The patient on the left with excessive generalized pigmentation has Addison's disease and the author on the right appears to have dysplastic nevus syndrome! Patients with dysplastic nevus syndrome are easily recognized by the presence of numerous melanocytic lesions on the skin which are larger than normal acquired nevi (greater than 6 mm), have irregular margins, are multi-hued, may occur in families, and appear to be a marker or precursor lesion for the development of malignant melanoma.

Despite enormous efforts by the American Cancer Society and interested physicians to spread the word about this important phenotype, many patients are not appropriately screened for the presence of malignant melanoma. With dozens, or even hundreds of lesions like those noted in the photograph on figure 1, it is not enough that patients be

instructed to follow themselves for change in any particular lesion. Serial photographs are necessary to document and identify early change which may signal the development of malignant melanoma. When identified early, malignant melanoma is easily cured by simple excision. All patients who resemble the phenotype illustrated in figure 1 should be screened by dermatologists and followed with serial photography. The usefulness of this approach is well established. The tragedy of metastatic malignant melanoma occurs all too often in our society.

Claude S. Burton, M.D.
Pigmented Lesion Clinic
Duke University Medical Center
Durham 27710

#### The Doctor/Patient Responds

#### To The Editor:

Dr. Burton is quite correct. Despite a negative family history for cutaneous malignancy, my numerous atypical nevi put me at increased risk for developing malignant melanoma. I currently adhere to the regimen of baseline photography, dermatologic surveillance and sunscreen recommended for patients with dysplastic nevi. 1, 2

In addition to Dr. Burton's letter, I received several other letters and even a telephone call alerting me to the dysplastic appearance of my nevi. I appreciate the generosity of spirit shown by those physicians who took the time to express their care and concern for me. People wrote in varied ways, some lightly, some seriously, some even apologetically for "poking their nose into my business."

It was a difficult transition to undergo, from the physician who made an unexpected diagnosis into a patient, myself, possessor of the unexpected diagnosis. Indeed, I have been reminded by this experience that the patient who is receiving an unanticipated diagnosis will benefit markedly from a gentle and thoughtful offering of the information. The transition into "patienthood" is rarely easy. By putting ourselves momentarily in the position of the patient (as I did, ever so accidentally, in this instance), we as physicians may be better able to address the needs of our patients to whom we are delivering unexpected news.

Mark Linzer, M.D.
Division of General Medicine
Duke University Medical Center
Durham 27710

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#### Editor's Note:

I found the above exchange of letters delightful. It's just possible that Drs. Linzer and Burton are as good as their young colleagues think they are.

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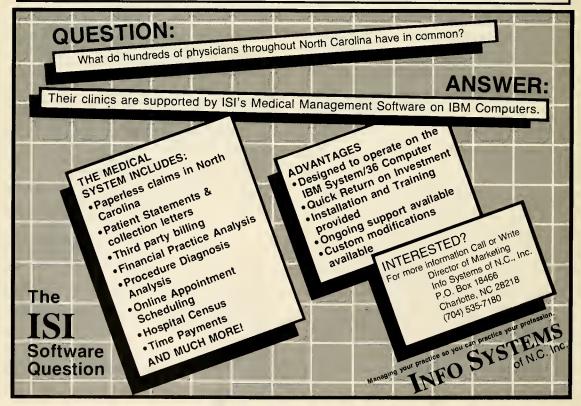
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## A defense against cancer can be cooked up in your kitchen.



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Foods high in fats, salt- or nitrite-cured foods like ham, and

There is evidence that diet and cancer are related. Some foods may promote cancer, while others may protect you from it.

Foods related to lowering the risk of cancer of the larynx and esophagus all have high amounts of carotene, a form of Vitamin A which is in cantaloupes, peaches, broccoli, spinach, all dark green leafy vegetables, sweet potatoes, carrots, pumpkin, winter squash and tomatoes, citrus fruits and brussels sprouts.

Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.



types of sausages smoked by traditional methods should be eaten in moderation.

Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat.
Weight reduction may lower cancer risk. Our 12- year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

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#### In Memoriam

#### Leon Norris Ogburn, M.D.

Leon N. Ogburn was born September 6, 1913 in Harnett County. He died on August 28, 1985 following a long illness.

Dr. Ogburn was a graduate of Campbell University and Wake Forest University. He received his medical degree from Temple University Medical School in 1941. He served his residency at James Walker Hospital in Wilmington, and he served his country in the United States Army from September 15, 1941 to August 21, 1944.

Following his military service, Dr. Ogburn was a mine physician for Glen Burnie Collieries and a private physician in Shamokin, Pennsylvania for ten years. In 1953, he returned to North Carolina and began the practice of general medicine in Raleigh, which lasted until 1985. He was a physician at Westinghouse Meter Plant from 1953 to 1973 and at Monsanto, Research Triangle Park, from 1954 to 1973.

Dr. Ogburn was past president of Carolina Industrial Medical Association, past treasurer of the Wake County Medical Society, and former board member of the Wake County Cancer Society. Dr. Ogburn was a 32nd degree Mason and Shriner and a member of the Square Club at Westinghouse.

Dr. Ogburn is survived by his wife, Mrs. Marcelene S. Ogburn; one son, John Leon Ogburn of Raleigh; three daughters, Mrs. Linda Smith, Mrs. Kathy Roebuck, and Mrs. Lisa Taylor, all of Raleigh; four sisters and six grand-children.

Dr. Ogburn will be sorely missed by his medical colleagues and his faithful and appreciative patients. He was a fine physician and his devotion to his patients and to humanity was exemplary.

#### David Raft, M.D., 1930-1985

It's hard to talk about David because we're so devastated by our loss. But I think he would have wanted us to share our feelings, our memories and what we learned from knowing him.

David was a singular individual, a very private and sensitive person. He was a gentle, kind man who frustrated those of us who tried to kindle some vestige of grandiosity in him. He was opposed to any chauvinism except for UNC basketball. There was no group which he wanted to be head of and no one he didn't want to encourage and inspire, including people who were regarded as rather difficult. He seldom gave up on people.

He was a gifted teacher who always had a penetrating insight based on a clinical or personal experience to contribute on virtually any issue. He was equally comfortable with internal medicine, psychopharmacology and psychoanalysis or any combination of those. He could and

would respond to emergencies with the same generosity and excellence he showed in providing psychoanalytic supervision. He also had a taste for music, modern dance, art, fine food and introduced me to more than one good wine. He was a devoted husband and father.

David was notable in another way: from the time I first met him as a resident on South wing to the last time I saw him on Tuesday afternoon — sitting in bed and going over a pile of mail between his legs — he never stopped working and he never stopped growing. At first he was an eager but unassuming pupil, then a loyal comrade, and in the last few years a wise father to me and to many others. Even when he was seriously ill in the hospital, junior and senior faculty including me would come by to cheer him up and find ourselves seeking his advice about problems in the department. He never relinquished his many roles, including the one of curious observer of his own emotional responses. His prolific writing in recent months is testimony to his success in battling his energy-depleting illness.

He leaves us a rich model of clinician-teacher and researcher but above all of a compassionate human being who personified what we strive for but fail to achieve — a dignity, courage and consideration for others in the face of untimely illness and death. He would want us to rededicate ourselves to those ideals of service to patients and collegial behavior which he so naturally lived.

Just before his cancer was diagnosed David mentioned a very pleasant image he had carried in his mind of a farm: a patchwork of brightly colored kerchiefs on the heads of tomato pickers against a green field. David already strongly suspected the diagnosis and his vision was I believe the persistent hope rising in his heart that something bright could flourish in spite of the shortened span of his life. I believe David was successful and I think he died with that enjoyable image before him.

> Roger Spencer, M.D. Oct 16, 1985

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Place: Chapel Hill

Credit: 7 hours Category I AMA

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514, 919/962-2118 Info:

#### February 12

Affective Disorders: Diagnosis and Treatment

Place: Greenville

Credit: 3.5 hours Category I AMA

Fee: \$30

Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/ Info:

758-5200, ext. 208

#### February 13-14

Laser Workshop in Neurosurgery

Chapel Hill Place:

15 hours Category I AMA Credit:

\$750

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27514. 919/962-2118

#### February 14-15

House Officer Selection

Place: Chapel Hill Credit: 12 hours Category I AMA

Fee: \$335

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27514, 919/962-2118

#### February 14-16

Family Physicians Weekend Place: Raleigh

Credit:

8 hours prescribed Mary Anna Hendley, NC Academy of Family Physicians, Box Info:

20146, Raleigh 27619, 919/781-6467

#### February 21

Pediatrics Day 1986

Greenville

Credit: 6 hours Category I AMA

Info: Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/

758-5200. ext. 208

#### March 6-7

Damaged DNA: Its Structure and Recognition

Place: Chapel Hill

Info: Pam Upchurch, Lineberger Cancer Research Center, UNC,

Chapel Hill 27514 919/966-3036

#### March 6-13

Review of Clinical Chemistry for Practicing Pathologists and Clinical

Chemists Place:

Greenville Credit: 40 hours Category I AMA

Fee:

Info: Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/

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#### March 9-14

Fellowships in Family Medicine

Place: Chapel Hill

Credit:

100 hours Category I AMA W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill Info:

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#### March 10-11

Advanced Cardiac Life Support

Place:

Chapel Hill W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill Info:

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#### March 12

Family Practice Update 1986: A Symposium on Pain

Place: Greenville

Credit: 7 hours Category I AMA

Fee: \$55

Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/ Info:

758-5200, ext. 208

#### March 12-15

Internal Medicine 1986

Chapel Hill Place:

Credit: 25 hours Category I AMA \$250

Fee:

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514, 919/962-2118 Info:

#### March 18-22

Infection Control Workshop

Place: Chapel Hill

Credit:

35 hours Category I AMA W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill Info:

27514. 919/962-2118

#### March 29

Seventh Annual Pulmonary Disease Update

Place: Greenville

Credit: 6 hours Category 1 AMA

Fee:

Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/

758-5200, ext. 208

#### OUT OF STATE

#### January 24-26

Winter Conference on Geriatrics Place: Hot Springs, VA

Mary Anna Hendley, NC Academy of Family Physicians, Box 20146, Raleigh 27619. 919/781-6467

#### February 1-5

Dermatology for Non-Dermatologists

Place:

Acapulco, Mexico Division of Dermatology, Box 3135, DUMC, Durham 27710. 919/684-2504

#### February 1-8

Urologic Update
Place: Vail, CO
Credit: 25 hours Category I AMA Linda Mace, Box 3707, DUMC, Durham 27710. 919/684-8111

#### February 6-8

Advanced Ultrasound Seminar

Place:

Lake Buena Vista, FL
Dr. Frederick W. Kremkan, Center for Medical Ultrasound,

Bowman Gray, Winston-Salem 27103, 919/748-4505

#### February 15-20

Postgraduate Course in Diagnostic Imaging

Ixtapa, Mexico 22.5 hours Category I AMA Credit:

Fee: \$475

Carl E. Ravin, M.D., Box 3808 DUMC, Durham 27710, 919/681-2711, ext. 226

1986 Annual Meeting and Scientific Session, Virgina Chapter, AAP and

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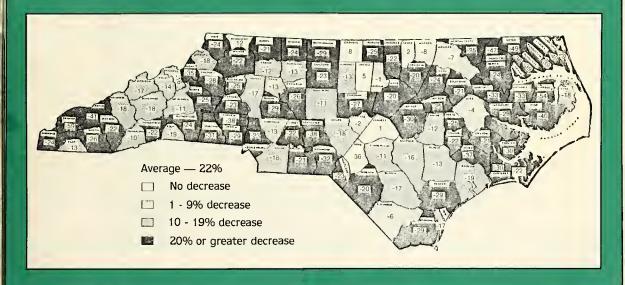
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### North Carolina

MEDICAL JOURNAL

for doctors and their patients

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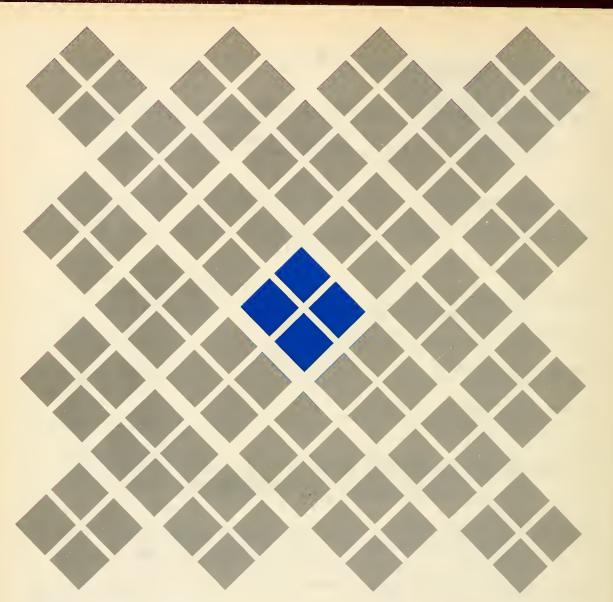
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#### Early Neonatal Back Transfer

Arthur E. Kopelman, M.D., Rita L. Saldanha, M.D., Michael D. Cruze, M.S., and John E. Wimmer, Jr., M.D.

 Transferring premature or ill newborn babies back to their local hospital once they are stable has proven to be both safe and effective.

tertiary level perinatal center was developed at Pitt A County Memorial Hospital/East Carolina University School of Medicine in Greenville several years ago because of unmet needs for services including neonatal intensive care in rural eastern North Carolina. Despite the ongoing addition of personnel and new beds, the Neonatal Intensive Care Unit as originally operated could not meet all the newborn intensive care needs in eastern North Carolina. In response, a policy of transferring premature or ill newborns from our Neonatal Intensive Care Unit to their local hospital "as early as possible" evolved. Most physicians and community hospitals cooperated in accepting their infants back as a way they could help to relieve the severe shortage of Neonatal Intensive Care Unit beds. We evaluated back transfers during 1983 retrospectively to evaluate their impact on Neonatal Intensive Care Unit bed availability and to identify problems associated with this policy.

#### The Back Transfer

We decided when a particular infant could safely be transferred to a local hospital based on our knowledge of that hospital's facilities. A neonatal outreach education program helped us to become aware of each hospital's capabilities as our outreach teachers tried to help extend the local hospital's abilities. A physician to physician telephone conversation preceded each back transfer decision. After we described the care needs (monitoring, gavage feedings, etc.) of the infant, the receiving physician decided whether he and his nursing staff could safely handle the infant. Other steps that preceded every back transfer are listed in table 1.

We consider stable premature infants on feedings to be candidates for transfer if they do not have respiratory distress or require supplemental oxygen. Most of our community hospitals can now monitor infants having occasional apnea/bradycardia, can administer theophylline, do theophylline blood levels, and do gavage feedings. Other infants with a wide variety of problems are also considered candidates for back transfer.

#### Study Methods

We reviewed records of all infants admitted to our Neonatal Intensive Care Unit during 1983 using a computerized data base. Admission weight and route of admission Table 1
Required For Back Transfer

- 1. Phone receiving physician
- 2. Phone receiving nursery nurses
- 3. Discharge summary
- 4. Eye exam, hearing screen
- 5. Parent's consent
- 6. Parent education

(local Pitt County patient, feto-maternal transfer, outborn neonatal transport) were noted, as was the county of residence. We also determined which infants were back transferred and the infants' weights both on admission and at the time of back transfer or discharge. We also reviewed readmissions of infants to the Neonatal Intensive Care Unit following back transfer.

We conservatively estimated the length of stay of back transferred infants at local hospitals as follows. We projected the number of days it would take for each infant to grow from his weight at the time of back transfer to a projected discharge weight of 2000 g, our usual discharge weight, using a standardized premature infant growth chart. If the infant weighed over 2000 g at back transfer we estimated a need for five further days of hospitalization; we do not arrange back transfer for an infant who will be ready for discharge within 1-2 days. We consider these approximations of further hospital days to be very conservative.

#### Results

Of the 515 infants admitted to the Neonatal Intensive Care Unit in 1983, 20% were Pitt County infants, 39% were feto-maternal referrals delivered in our hospital, and 25% were neonatal transfers. The remaining 15% were out-of-county infants from our region who had been transferred to (or born at) other tertiary centers when we lacked available beds, and were subsequently re-transferred to our Neonatal Intensive Care Unit because it was closer to the parents' residence. The outcome for all 515 infants is shown in figure 1.

Of the 354 surviving infants from other counties, 163 or 46% were back transferred. Forty-three infants were not eligible for back transfer because they came from counties without a hospital. While infants are admitted to the Neonatal Intensive Care Unit with a variety of medical and

From the Department of Pediatrics, East Carolina University School of Medicine, Greenville 27834.

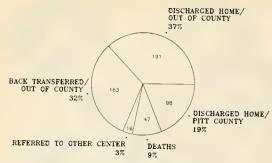


Figure 1. Outcome for 515 infants admitted to our Neonatal Intensive Care Unit in 1983.

surgical problems, disorders associated with prematurity are the commonest reason for admission. Figure 2 shows the transfer weights of the 163 back transferred infants, many of which were well below our customary discharge weight of 2000 g.

#### Beds Freed Up by Back Transfer

The 163 infants back transferred left our Neonatal Intensive Care Unit following an average hospitalization of 14 days and, very conservatively (see Methods), spent an average of 17 additional days in their community hospitals before discharge. Thus, 2,771 patient days (163 infants × 17 days/infant) were freed up in the Neonatal Intensive Care Unit during 1983 as a result of back transfer, making it possible for our unit to provide care for an additional 163 infants in 1983 (since the average length of stay for all infants admitted in 1983 also happened to be 17 days and our unit operates at 100% of capacity). Without back transfer only 352 infants could have been accommodated. Back transfer therefore made it possible for us to provide neonatal intensive care to 46% more infants than would otherwise have been possible, 515 rather than 352.

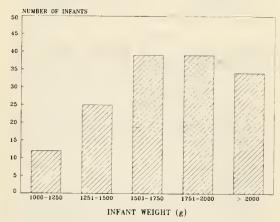


Figure 2. Weight of all 163 infants at the time of back transfer to their local hospitals in 1983.

#### Problems Encountered with Back Transfer

Three of the 163 back transferred infants (1.8%) developed problems at the community hospitals which necessitated readmission to the Neonatal Intensive Care Unit: necrotizing enterocolitis, aspiration pneumonia associated with apnea, and late onset hydrocephalus following a known intraventricular hemorrhage. None died. It is not clear if the episode of aspiration would have occurred as well in the Neonatal Intensive Care Unit, but it is likely that the other two problems would have occurred without back transfer.

#### Discussion

A regional neonatal program provides appropriate care for all newborn infants within a geographic region. Emphasis has been placed on the referral and transport of patients to the tertiary center, but the back transfer of newborns to their community hospitals is also important and serves a variety of purposes (table 2). The need for routine early back transfer of infants becomes crucial, however, when there is a scarcity of neonatal intensive care beds.

A considerable financial savings resulted from providing care at community hospitals rather than in our tertiary center; Bose<sup>1</sup> and others<sup>2</sup> have recently reported savings associated with early back transfer of infants.

The risks incurred in back transfer also need to be considered. This was a real concern for us since our Neonatal Intensive Care Unit serves a geographically rural region of eastern North Carolina and is the referral center for 21 small to medium-sized community hospitals, and an outreach education program on neonatal care has only been available since 1982. It was therefore gratifying that only three of the 163 back transferred infants (1.8%) needed to return to the Neonatal Intensive Care Unit for treatment. This compares with a previous description of early back transfer in which two percent of back transferred infants needed to be returned to the Neonatal Intensive Care Unit after new problems developed at the local hospital.3, 4 Following back transfer several infants developed other problems, including feeding difficulties, anemia, increasing frequency of apnea/bradycardia spells, and patent ductus arteriosus, all of which could be handled by physicians at the community hospitals with telephone communication and support from the neonatologists. Ongoing support and the acceptance of the fact that occasional infants will require re-transfer to the Neonatal Intensive Care Unit are necessary for early back transfer to be successful. The types of clinical problems that may be encountered at community hospitals caring for back transferred infants are similar to those encountered

#### Table 2 Rationale for Back Transfers

- 1. Free-up beds at tertiary center.
- 2. More appropriate use of limited resources.
- Maintain skills of doctors and nurses at community hospitals.
- 4. Reduce overall costs.
- 5. Increase contact between parents and infant.

#### Table 3 Neonatal Problems Cared for at Community Hospitals

Premature care temperature regulation gavage feeding observe for signs of feeding intolerance ostomy care Apnea/bradycardia management monitoring heart rate and respirations use of theophylline, drug levels arrange for and educate parents about home monitoring Hyperbilirubinemia phototherapy monitor elevated direct bilirubin following hyperalimentation Sepsis complete course of antibiotics Neurologic problems anticonvulsant monitoring assess for development of hydrocephalus continue family evaluation and support arrange financial and nutritional services arrange foster placement or adoption

regularly in intermediate or convalescent nurseries, and will be included in further outreach education efforts (table 3). Table 4 lists the potential or actual obstacles to back transfer.

#### Table 4 Obstacles to Back Transfer

- Perinatal funds only available for care at tertiary center.
   Hospital administration at community hospital may not
   want infants back.
   Parents may refuse to incur costs.
- 2. No funds to pay for the ambulance trip.
- Parental anxieties.
   Familiar with staff and policies at tertiary center.
   May lack confidence in community hospital.
- Suboptimal policies at community hospitals, e.g.: Admit infant to adult ICU.
- Restrict parent visitation.

  5. Primary physician resistance Lack of skills,
  Fear of litigation.

Back transfer has created a new problem for our neonatal intensive care unit. Every patient in our unit is critically ill. With more severe illness in the unit our per diem costs have risen. Means to pay for our rising costs must be addressed.

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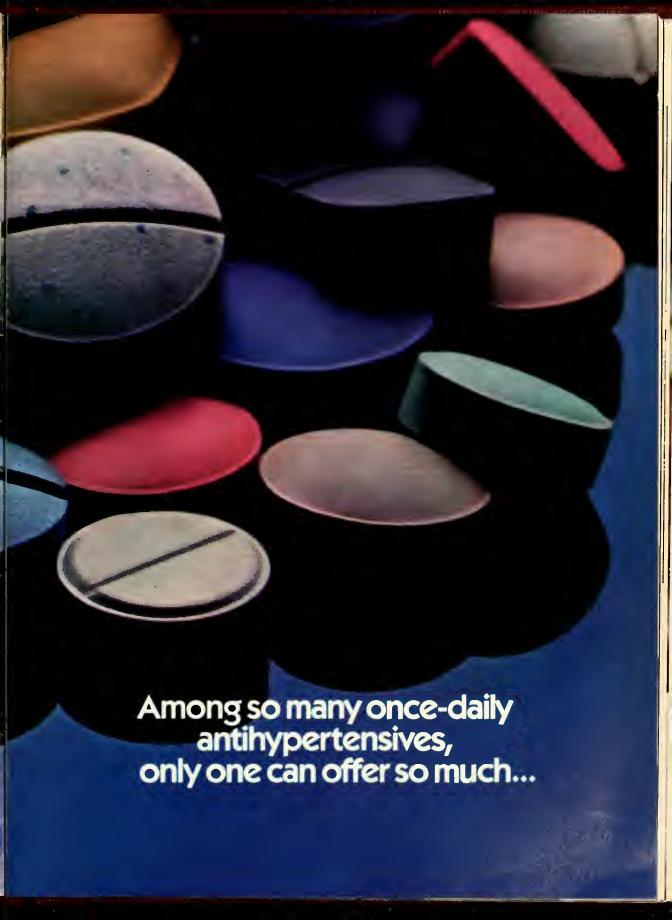


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WARNINGS
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IN PATIENTS WITH ANGINA PECTORIS there have been reports of exacerbation of angina INPAILENTS WITH ANGINA PECTORIS there have been reports of exacerbation of angina and in some cases, myocardial infarction, following abrupt discontinuance of proprandial therapy. Therefore, when discontinuance of proprandial is planned the dosage should be gradually reduced and the patient carefully monitored in addition, when progranolot is prescribed for angina pectors, the patients should be cautioned against interruption or cessation of therapy without the physicians advice if progranolot frietapy is interrupted and exacerbation of angina occurs, disualty is advisable to reinstitute propranolot therapy and lake other measures appropriate for the management of unstable angina pactors. Since octionary aftery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease, who are given propranolot for other indications.

THYROTOXICOSIS Beta blockade may mask certain clinical signs of hyperthyroidism. Therefore, abrupt withdrawal of propranolol may be followed by an exacetration of symptoms of hyperthyroidism, including thyroid storm Propranolol does not disfort thyroid function tests. IN PATIENTS WITH WOLFF PARKINSON-WHITE SYNDROME several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a demand pacemaker. In one case this resulted after an initial dose of 5 mg propriation in the case of the propranolor o

requiring a defining position proportion of the proportion of the

Nonallergic Bronchospasm (eg, chronic bronchitis, emphysema) —PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RÉCEIVE BETA BLOCKERS INDERAL should be administered with caution since it may block bronchodifation produced by endogenous and exogenous catecholamine stimulation of beta receptors

DIABETES AND HYPOGLYCEMIA Bet authoration to be a teceptors ance of certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in fabilitie insulin-dependent diabetes in these patients it may be more difficult to adjust the dosage of insulin. Hypoglycemic attacks may be accompanied by a precipitous elevation of blood pressure.

Theardes should be used with caution in severe renal disease. In patients with renal disease thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects.

Iniazides may precipitate azotemia in patients with impaired renal function, cumulative effects of the drug may develop. Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral adrenergic-blocking drugs. Sensitivity reactions may occur in patients with a history of allergy or bronchall asthma. The possibility of exacerbation or activation of systemic lupus erythematosus has been renorted.

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CARCINDGENESIS MUTAGENESIS, IMPAIRMENT OF FERTILITY Long-term studies in CARCINDGENESIS MUTAGENESIS, IMPAIRMENT OF FERTILITY Long-term studies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies in both rats and mice employing doess up to 150 mg/kg/day, these was no evidence of significant druig-induced texticit. There were no drug-retaled tumonigenic effects at any of the dosage levels. Perproductive studies in animals did not show any impairment of tertifity that was attributable to the drug.

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PEDIATRIC USE Satety and effectiveness in children have not been established 
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serum and urine efectrolyte determinations are particularly important when the patient is
somitting excessively or receiving parenteral fluids. Medication such as digitalis may also
influence serum efectrolytes. Warning signs irrespective of cause are Dryness of mouth thirst,
weakness lethargy drowsiness resiliessness, muscle pains or cramps muscular fatigue,
hypotension, oliguria tachycardia and gastrointestinal disturbances such as nausea and
comitting

weakness lethargy drowsness (esilessness, muscle pains or cramps muscular latigue, hypodesion, oligural achycardia and gastrointestianal disturbances such as nausea and venting.

Hypokalemia may develop especially with brisk druesis, when severe cirrhosis is present or during concomitant use of corticosteroids or ACTH.

Interference with adequate oral electrolyte intake will also contribute to hypokalemia hypokalemia can sensifize or exaggerate the response of the heart to the toxic effect of digitalis (e.g. increased ventricular irritaloritalis). Hypokalemia may be avoided or treated by use of polassium supprements, such as foods with a high potassium content.

Any chloride deficit is generally mild and usually does not require specific treatment and the strandinary circumstances (as in liver or renat disease). Ditulional hypohalemia is extraordinary circumstances (as in liver or renat disease). Ditulional hypohalemia is extraordinary circumstances (as in liver or renat disease). Ditulional hypohalemia is extraordinary circumstances (as in liver or renat disease). Ditulional hypohalemia is extraordinary circumstances and propriate the placement is the therapy of choice.

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#### ADVERSE REACTIONS

Propranolol hydrochloride (INDERAL\*): Most adverse effects have been mild and transient and have rarely required the withdrawal of

therapy
Cardiovascular Bradycardia congestive heart failure intensification of AV block, hypotension paresthesia of hands, thrombocytopenic purpura arterial insufficiency, usually of the Raynaud type
Cential Nervous System Lightheadedness, mental depression manifested by insominal assitude weakness, latigue reversible mental depression progressing to catalonia, visual disturbances, hallucinations, an acute reversible syndrome characterized by disonentation for time and place short-term memory loss emotional fability slightly clouded sensorium, and decreased performance on neuropsychometrics
Gastroinestimal. Nausea, vomling, epigastinc distress, abdominal cramping distribea, constipation, mesentieric arterial thrombosis, ischemic colitis.
Allergic Pharyngitis and agiranulocytosis erythematous rash, lever combined with aching and sore linoal, laryngospasm and respiratory distress.
Respiratory Bronchospasm
Hematologic. Agranulocytosis: nonthrombocytopenic purpura: thrombocytopenic purpura.

Auto-Immune in extremely rare instances, systemic lupus erythematosus has been

reported

Mscellaneous Alopecia, LE-like reactions psonasiform tashes, dry eyes, male impotence and Peyronies disease have been reported rarely. Dculomucocutaneous reactions
involving the skin serious membranes, and conjunctivae reported for a beta blocker (practolol)
have not been associated with propranolol.

Mustics/blockible/ide-.

ydrochlorothlazide: astroniestina! Andrewa gastric irritation, nausea vomiting, cramping, diarrhea constipa-in, jaundice (intrahepatic cholestatic jaundice), pancreatitis, sialademits Central Nervous System Dizziness, vertigo, panesihesias, headache xanthopsia Hemafologic Leukopenia, agranulocytosis, thrombocytopenia apilastic anemia Carriolvascular Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or transfer).

narcotics) Hypersensitivity Purpura photosensitivity rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis), lever, respiratory distress, including pneumonitis, anaphylactic

Considered vascinistics, rever, respiratory visities, including prieditionins, analympacini reactions.

Other Hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restless-ness, transient blurred vision.

Whenever adverse reactions are moderate or severe thiazide dosage should be reduced.

or therapy withdrawn

5112/985



# Distraction by Technology: A Ventricular Mass in a Patient with Pheochromocytoma

Peter W. Robie, M.D.

 Despite their many advantages, technological advances can sidetrack the physician in search of a diagnosis.

PHEOCHROMOCYTOMA, an uncommon cause of cardiovascular disease, must be diagnosed and treated promptly to avert potentially fatal hypertensive crises and myocarditis. Unfortunately, most patients have a bewildering variety of symptoms and physical findings that make early diagnosis difficult and may lead one in the pursuit of other diseases. This is the story of a patient in whom a ventricular mass was found before the diagnosis of pheochromocytoma was made.

A 23-year-old black man was referred to the North Carolina Baptist Hospital with a two week history of shortness of breath, orthopnea, and edema of his legs. There was no prior history of heart disease. Past history included a partial gastrectomy at age 15 for peptic ulcer disease, cross-fused left kidney with proteinuria, and iron deficiency anemia. The last recorded blood pressure, at age 14, was 136/94.

The patient had severe respiratory distress and orthopnea. Vital signs were blood pressure 150/120 mm Hg, pulse = 119, respirations = 40, temperature = 99°. The optic fundi were normal. There were diffuse lung rales with bibasilar dullness, an enlarged heart with summation gallop, mild hepatomegaly, and massive pitting edema of the legs. Laboratory tests showed a microcytic anemia with a hematocrit of 35%, a serum sodium of 125 mg/dl, and hematuria. Chest x-ray showed cardiomegaly, pulmonary edema and a right middle lobe infiltrate. Electrocardiogram showed sinus tachycardia with left axis deviation, nonspecific T wave changes, and low voltage.

Initial treatment included nasal oxygen, furosemide, methyldopa and apresoline. Six hours after admission his blood pressure rose to 170/130; a continuous infusion of nitroprusside lowered it to 150/100. At that time, the possibility of pheochromocytoma was raised but not pursued.

On the following day, an echocardiogram (figure 1) revealed a 2.5 cm pedunculated mass with a lucent center in the left ventricle, and a 2.8 cm mass in the inferior vena cava. A perfusion lung scan showed apical filling defects consistent with pulmonary emboli at a 75% probability.

Catheterization of the ascending aorta revealed a dilated hypocontractile left ventricle with normal coronary arteries. Inferior vena cavagram and aortogram showed a 4 cm right adrenal tumor with extension into the inferior vena cava. The patient had no hypertension during the catheterization study.

A computerized tomographic scan of the chest and abdomen on the next day confirmed the presence of a right adrenal mass and findings consistent with a thrombus in the left ventricle. A twelve hour urine assay for vanillylmandelic acid equalled 30.1 mg/g of creatinine (normal 1-8 mg/g); subsequent serum total cathecholamines were 4,179 pg/ml (normal 104-740 pg/ml), serum norepinephrine was 9,068 pg/ml (normal 104-548 pg/ml), and serum epinephrine was 212 pg/ml (normal 0-88 pg/ml).

After seven days of oral phenoxybenzamine and methyltyrosine, a 5 cm tumor was surgically removed from the inferior vena cava and the right adrenal gland. Microscopic pathology confirmed pheochromocytoma, with predominantly norepinephrine granules. Postoperatively, repeat 24-hour urine assays showed a vanillylmandelic acid of 2.2 mg/g of creatinine and urine metanephrines of 0.6 mg/g of creatinine (normal 0-1.3). Two weeks later, after an uneventful recovery, an echocardiogram showed complete resolution of the ventricular mass.

#### Comment

Pheochromocytomas frequently have multiple, unusual presentations. Typical symptoms, when present, include episodic pounding headache with palpitations and diaphoresis; flushing is uncommon. The blood pressure is usually elevated during these episodes, with normal blood pressure at other times; many patients present with fixed rather than episodic hypertension. An elevated 24-hour urine metanephrine study will suggest the diagnosis. The recently described clonidine suppression test, in which plasma catecholamines drop to less than 500 pg/ml after 0.3 mg of oral clonidine in normal patients but do not fall in patients with pheochromocytoma, may become a more useful screening test in the future. Tumor localization studies include computerized tomographic scanning of the

From the Bowman Gray School of Medicine of Wake Forest University, 300 Hawthorne Road, Winston-Salem 27103.



**Figure 1.** Left ventricular mass (M). LV — left ventricle; IVS — interventricular septum; MV — mitral valve; LA — left atrium.

abdomen, aortography and nuclear scanning.2

Patients with pheochromocytoma may have cardiac involvement, usually a hypertensive congestive cardiomyopathy, or a necrotizing myocarditis due to high circulating levels of catecholamines.<sup>3</sup> Echocardiography will show a diffuse cardiomyopathy which may improve after successful treatment.<sup>4</sup> Rarely, severe elevations in the blood pressure will precipitate an acute myocardial infarction.<sup>5</sup> Direct involvement of the heart by pheochromocytoma, however, is distinctly rare. A recent review of intrathoracic pheochromocytomas showed that 29/33 cases occurred in the sympathetic neural chain in the posterior mediastinum, three involved the pericardium, and one involved the aortic plexus.<sup>6</sup> There has been one report of pheochromocytoma involving the interatrial septum.<sup>7</sup>

The ventricular mass in this patient was unexpected and led to immediate invasive testing to explain its origin. A differential diagnosis of primary ventricular masses includes myxomas, fibromas, sarcomas, or thrombi masquerading as pseudotumors; occasionally, primary intracardiac tumors may also have associated thrombi. Metastatic tumors grow in the myocardium and rarely involve the endocardial surface. Ventricular tumors are difficult to distinguish on echocardiogram from thrombus. Typically, tumors are pendunculated and thrombi are laminated; as this case illustrated, however, distinctions between tumor and thrombus may be unreliable. There has

been no reported case of pheochromocytoma involving the endocardium.

Should the diagnosis of pheochromocytoma have been made earlier? A recent study of diagnostic errors by physicians and housestaff in an academic medical center classified diagnostic errors into four categories: errors of omission, when significant clinical clues were ignored; errors of premature closure, when a diagnosis was not fully justified by existing clinical data; errors of incorrect synthesis, when the available data contradicted the conclusion; and errors of inadequate synthesis, when conclusions that could be supported by clinical data were not drawn. Errors in premature closure were the most common problem seen, irrespective of level of training. 9 In evaluating our patient, the impact of the echocardiogram report may have distracted us from pursuing pheochromocytoma, an error of both omission and premature closure. With the large array of sophisticated imaging techniques currently available, it is easy to allow unexpected or dramatic results to suggest diagnoses that on further reflection may not be supported by the clinical presentation. 10

When evaluating any seriously ill patient, one should not overemphasize an unexpected or unusual test report; despite the rapid advances being made in imaging, a differential diagnosis should always be primarily based on the patient's history and physical exam, and not on the basis only of an unexpected test result.<sup>11</sup>

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#### A Little Bit of Obstetrics For All of Us

William N. P. Herbert, M.D.

THE many advancements in medicine over recent decades have made mothers and their babies healthier. As the outcome of pregnancies complicated by medical and surgical disorders has improved, attention has now turned toward the area of preventing complications, especially congenital malformations. Unfortunately, the 2-3% rate of severe or disabling birth defects has remained constant for many years. Preconceptional care — counseling and planning — is one approach in addressing this issue.

Robert C. Cefalo, M.D., Ph.D., Professor and Director of the Division of Maternal and Fetal Medicine, Department of Obstetrics and Gynecology at UNC, has been at the forefront of this aspect of obstetrical care and has established a separate clinic in which women can be counseled regarding the association between pregnancy and medical conditions, exposure to a variety of environmental agents and lifestyle (diet, hobbies).

That the state of health prior to pregnancy has an important role in obstetrical outcome can be clearly shown in a variety of situations. For example, the frequency of congenital malformations in offspring of diabetics can be reduced from 5-6% to 3-4% when patients are in strict glucose control before and early in gestation. In patients with epilepsy, reduction or elimination of possible teratogenic drugs, e.g., diphenylhydantoin and valproic acid, when possible, minimizes the risk of congenital defects. Patients with known phenylketonuria should have a phenylalanine

blood level down to 4-6 mg/dl prior to conception since an elevated phenylalanine level can adversely affect brain development in an otherwise normal fetus. Exposure to a variety of environmental agents, such as lead and mercury, can adversely affect pregnancy outcome.

Smoking and alcohol consumption are lifestyle habits that can have major impact on obstetric outcome and should be avoided during gestation. Avoidance of the many overthe-counter drugs we Americans consume should be advised when a couple is contemplating pregnancy.

Information is continuing to accrue that stresses the need for proper diet and nutrient intake in the periconceptional period. In the near future, vitamin and mineral supplementation, so long an obstetrics tradition *during* pregnancy, may be rountinely advised *before* pregnancy!

The effects of vigorous exercise early in pregnancy is becoming increasingly important as Americans pursue the "get in shape — stay in shape" attitude of recent years. Yet, the potential for hyperthermia exists which may be harmful to an embryo or developing fetus.

Physicians in all specialties should be aware of the importance of preconceptional health, and they should advise patients who are contemplating pregnancy to improve the likelihood of a successful outcome by eliminating unnecessary over-the-counter drugs, by avoiding alcohol and smoking, by having chronic diseases (such as diabetes and epilepsy) in "good shape," and by paying attention to nutrition and diet.

This aspect of medicine makes all of us part-time obstetricians whose efforts will have significant impact on our children of tomorrow.

From the Division of Maternal & Fetal Medicine, Department of Obstetrics & Gynecology, UNC School of Medicine, Chapel Hill 27514.

### The Significance of Automated Systems for Detecting Significant Bacteriuria

Stephen R. Nichols, M.D., and Francis A. Neelon, M.D.

 Use modern laboratory tests wisely without losing sight of the patient behind the specimen.

IT is a common occurrence: a woman comes to see the doctor because her urine smells foul and "burns" or "stings" when she passes it, which she must do frequently. If the situation has gone unattended too long, she may also complain of back or side pain, fever and chills. The physician will obtain a urine specimen for study. If the specimen is sent to a modern clinical laboratory for analysis, it may be automatically processed by a machine developed specifically to screen urine specimens for significant bacteriuria quicker and easier than standard plate-culture techniques allow. Isn't the march of progress wonderful? Not necessarily - lemmings march a great many miles and overcome astounding obstacles only to drown in the sea. Theirs is surely a spectacular journey, but not one that we would choose to duplicate entirely. Fortunately for Lemmus lemmus, some of them do not blindly follow the path, wherein lies our lesson. In this article we take a look at automated systems that screen urine specimens for bacteriuria and the pitfalls their use can provide.

#### Techniques for Determining Bacteriuria Automatically

Photometry and bioluminescence are the two techniques most commonly employed in commercially available automated screening systems. Photometry measures the amount of light passing through a given specimen and correlates this with the turbidity of the specimen. Urine turbidity is caused by bacteria, as well as by other constituents of urine sediment (epithelial cells, crystals, debris, and so forth); therefore, the amount of bacteria present in a given specimen is determined by photometric analysis of the specimen before and after an incubation period during which any bacteria present can multiply. Since only the bacterial component of urine turbidity should increase during the incubation, a considerable increase in turbidity during incubation identifies the presence of significant bacteriuria (see figure 1).

Bioluminescence is the conversion of biochemical energy in the form of adenosine triphosphate, or ATP, into radiant energy, or light. This conversion is accomplished by luciferin-luciferase, the enzyme system used by fireflies to generate their tail light. The light is produced by luciferin

when it is oxidized by the enzyme luciferase in a reaction requiring ATP and oxygen. By controlling the amount of oxygen going to their tail organ, fireflies can control the occurrence of the luciferin-luciferase reaction and, thus, the pattern of their flashing. This is important to fireflies since their flashing patterns are used to attract mates.

In order to study urine specimens by bioluminescent methods, the ATP must first be released from within cells and it must be released selectively from the bacteria as opposed to cells from the patient. In practice this is accomplished by the addition of a reagent that causes the release of ATP by the patient's cells; an ATPase enzyme is added, to neutralize this pool of ATP; then a reagent to release bacterial ATP and the luciferin-luciferase are added, con-

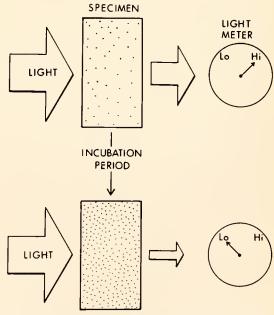


Figure 1. Detection of bacteriuria by decrease in light transmission. During the incubation period, viable bacteria multiply, causing a decrease in the amount of transmitted light relative to the initial value.

From the Department of Medicine, Duke University Medical Center, Durham 27710.

verting the pool of bacterial ATP into light which is measured by a simple photometer. If significant bacteriuria is present in the sample, then a considerable amount of ATP will be released and a considerable amount of light generated (see figure 2). For details on specific automated systems and descriptions of newer methods being developed, see the referenced articles by Pezzlo. 1, 2

#### Design Criteria of Automated Systems for Detecting Significant Bacteriuria

The basic design criteria for all automated bacteriuria detecting systems are 1) rapid analysis, 2) cost-effectiveness and 3) screening accuracy. The automated systems vary considerably in their turnaround times, ranging from 30 minutes to about nine hours, but all are an obvious improvement over the 18 or more hours required by conventional plate-culture techniques. Some of the newer automated methods can even provide results in just a few minutes, And Pezzlo has found them to be cost-effective. However, overall cost-effectiveness depends upon appropriate use of the automated systems and this can best be accomplished through a thorough understanding of the techniques involved and an appreciation of their limitations.

The screening accuracy of automated systems for detecting bacteriuria is very good, but "screening accuracy" has a hidden meaning and depends upon a hidden criterion. The hidden meaning lies in the definition of "screening" which implies that the test is not necessarily diagnostic or definitive if positive, but that the absence of the condition is very likely if the test is negative. Indeed, these automated systems have a very low false negative rate (less than 5%) so that those patients with any possibility of infection are detected. In order to achieve the low false negative rate, it is necessary to tolerate a higher false positive rate (20-30%) due to the characteristics of the tests. As a result, physicians can be confident of a negative result obtained in asymptomatic patients screened by one of these procedures; positive results need confirmation by a more specific test, such as plate-culture of a specimen obtained by careful cleancatch technique or bladder catheterization.

The hidden criterion is contained in the definition of "significant bacteriuria." Kass3 originally defined significant bacteriuria as greater than 100,000 bacteria per milliliter of urine and this is the standard used today. He found that less than 5% of patients with pyelonephritis had less than 100,000 bacteria per milliliter, while only 5% or so of asymptomatic female patients had greater than 100,000, so he established 100,000 as the cutoff point between contamination and infection. However, Stamm<sup>4</sup> has seriously questioned whether this definition should be applied to the case of acutely dysuric women. He proposes that the value for "significant bacteriuria" should be much lower in such cases, perhaps as low as 100 bacteria per milliliter. The major difference between the two populations studied by Kass and Stamm is the absence or presence of symptoms with a corresponding lesser or greater prevalence of infection. It is not surprising that the presence of symptoms should influence the point at which bacteriuria becomes "significant" because the appropriate clinical picture of a given disease state certainly increases the likelihood of that

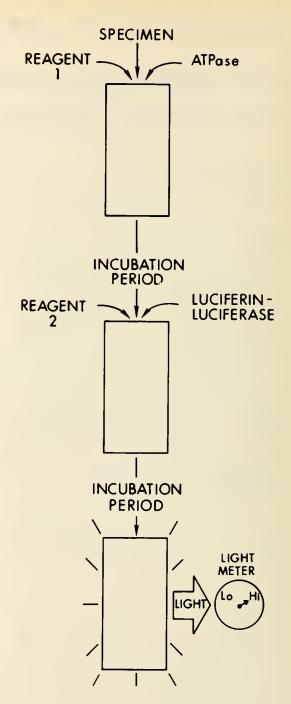


Figure 2. Detection of bacteriuria by generation of light from bacterial ATP. Specimen is briefly incubated with a reagent and ATP as to destroy any ATP not contained within bacteria. Then a second reagent lyses bacteria and firefly luciferin-luciferase generates light in proportion to the amount of ATP released (and therefore proportional to the amount of bacteria present in the specimen).

disease state as opposed to its likelihood in an inappropriate clinical picture. If a patient is symptomatic, even a 5% false negative rate cannot be tolerated, so automated screening should not be performed. The symptomatic patient should be investigated by plate-culture of a urine specimen obtained by meticulous clean-catch technique or bladder catheterization. Colony counts of greater than 10,000 in a symptomatic patient are *clinically* significant and Stamm suggests that colony counts as low as 100 may be significant.

#### A Case in Point

A 66-year-old black woman with a history of mild renal failure for over 20 years was seen at an outside hospital for evaluation after two days of the following symptoms: decreased urine output, dysuria, abdominal pain, chills, sweating, nausea and vomiting. The rest of her medical history was only relevant for "mild" diabetes for the past year and a half, untreated, and a symptomatic urinary tract infection one month prior to her current problems. At the outside hospital, she had a serum creatinine of 6.1 mg/100 ml (creatinine was 3.0 mg/100 ml one month earlier); glucose of 275 mg/100 ml; and white blood cell count of 28,000 with a marked left shift. The urine contained 4+ protein and was loaded with white blood cells, 3-5 red cells and 4+ bacteria. Urine culture grew greater than 100,000 E. coli sensitive to ampicillin. The patient was treated with piperacillin and her symptoms improved over two days, but her creatinine continued to climb to 8.9 mg/100 ml. She was transferred for further evaluation.

At transfer, she was relatively asymptomatic, but her white blood cell count was 27,300 with a marked left shift still present. Urinalysis revealed 3 + protein, numerous red cells, 4-5 white blood cells, and trace bacteria. A urine specimen was sent for culture, but was instead analyzed by bioluminescence and was reported back as "less than 10,000 colonies/ml." The patient's doctors realized that a

screening test for asymptomatic bacteriuria was inappropriate in this patient's case, so they disregarded the "negative" result and continued her antibiotic therapy. Although the patient in this case was asymptomatic when the second specimen was sent for culture, the presence of any bacteria in her urine would be a finding of significance, given the circumstances (previous history of symptoms, previous history of urinary tract infection, predisposing factor of diabetes, and partial treatment by antibiotics). Since it is beyond the design capability of automatic systems to detect less than 10,000 bacteria per milliliter of urine, their use in this case was inappropriate. Information that could be of use to the physician (namely the bacterial counts greater than zero but less than the cutoff point of the screening test, as well as antibiotic susceptibilities obtained from cultured specimens) is instead lost.

Bartlett and Galen<sup>5</sup> suggest that laboratory slips indicate whether a urine specimen is from a patient with or without symptoms as this would allow the clinical microbiology laboratory to handle the specimens appropriately, screening those from asymptomatic patients and culturing those from symptomatic patients. We agree that this would be helpful, but only in cases where the slips are accurately filled out so that no mixing of the two patient populations occurs. This can happen only if doctors understand the real value of using screening techniques in asymptomatic populations and the real drawbacks of their use in symptomatic patients.

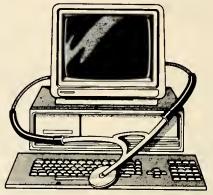
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Inducts and the decimagnitud by discretishment decides in 135 termic blood pressure and decreases in perpiheral resistance. Hemodynamic and Electrophysiologic Effects. Like other calcium antagonists, difluzione decreases sinanatrial and crivounticular conduction in isolated tissues and has a negative inotropic effect in isolated preparations. In the indicat animal, prolingation of the AH

in isolated proparations. In the intact animal, prolongation of the AH interval can be seen at higher doses. In man, diffuazem prevents spontaneous and ergonovine-provoked coronary artery spans. It causes a decrease in peripheral vascular resistance and a modest fall in blood pressure and, in exercise tolerance studies in patients with ischemic heart disease, reduces the heart rate-blood pressure product for any given work load. Studies to date, primarily in patients with good ventricular function, have not revealed evidence of a negative motorpic effect, cardiac output, ejection fraction, and left ventricular end disstolic pressure have not been affected. There are as yet few data on the interaction of dilitazem and beta-blockers. Resting hear trate is usually unchanged or slightly reduced by difftiazem.

of diffuzem and beta-blockers. Resting heart rate is usually unchanged or slightly reduced by diffuzem. Intravenous diffuzem in doses of 20 mg prolongs AH conduction intravenous diffuzem in doses of 300 mg of CARDIZEM node functional and effective refractory periods approximately 20%. In a study involving single oral doses of 300 mg of CARDIZEM in six normal volunteers, the average maximum PR prolongation was 14% with no instances of greater than first-degree AV block. Diffuzem-associated prolongation at the AH interval is not more pronounced in patients with first-degree heart block. In patients with sick sinus syndrome, diffuzem significantly prolongs sinus cycle length up to 50% in some cases.

Chronic oral administration of CARDIZEM in doses of up to 240 mg/day has resulted in small increases in PP interval, but has not usually produced abnormal prolongation. There were, however, three instances of second-degree AV block and one instance of third-degree AV block in a group of 959 chronically treated patients. Pharmacochinetics and Metabollism. Diffuzem is absorbed from the tablet formulation to about 80% of a reference capsule and is subject to an extensive instruction of an about 24%. CARDIZEM undergrees extensive hepatic metabolism in which 2% to 4% of the unchanged drug appears in the unner in who brinding studies show

unchanged drug appears in the unner in vitro tinding studies show CARDIZEM is 70% to 80% bound to plasma proteins. Competitive ligand binding studies have also shown CARDIZEM binding is not altered by therapeutic concentrations of digoxin, bydrochlorothizarde, pherylbutazone, propherabolis, salicytic acid, or wartarin. Single oral doses of 30 to 120 mg of CARDIZEM result in detectable plasma levels within 30 to 60 minutes and peak plasma levels two to three hours after drug administration. The plasma elimination half-life following single or multiple drug administration is approximately 3.5 hours. Desacetyl diltiazem is also present in the plasma at levels of 10% to 20% of the parent drug and is 25% to 50% as potent a coronary vasodifact as diffiazem. Therapeutic blood levels of CARDIZEM appear to be in the range of 50 to 200 mg/m. There is a departure from dose-linearity when single doses above 60 mg are given, a 120-mg dose gave blood levels three times that of the 60-mg are dose. There is no information about the effect of renal or hepatic impairment on excretion or metabolism of diltiazem.

#### INDICATIONS AND USAGE

1 Angina Pecteris Due to Coronary Artery Spasm, CARDIZEM

is indicated in the treatment of angina pectoris due to coronary artery spasm. CARDIZEM has been shown effective in the

artery spasm. CARDIZEM has been shown effective in the treatment of spontaneous coronary arter ypasm presenting as Prinzmetal's variant angine (resting angina with ST-segment elevation occurring during attacks).

2 Chronic Stable Angina (Classle Effort-Associated Angina). CARDIZEM is indicated in the management of chronic stable angina. CARDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise tolerance. There are no controlled studies of the effectiveness of the concomi-

tant use of dilitiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities

#### CONTRAINDICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus with second in the presence of a functioning ventricular pacemaker, (2) patients with second or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

#### WARNINGS

- Cardiac Conduction. CARDIZEM prolongs AV node refractory periods without significantly prolonging sinus node recov-ery time, except in patients with sick sinus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of Avoidation of the state of the
- inotinopie effect in isolated anti-Aussup preparations, hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). Experience with the use of CARDIZEM alone or in combination with beta-tiockers in patients with impaired ventricular function is very limited. Caution should be exercised when using the drug in such patients. Hypotension. Decreases in blood pressure associated with CARDIZEM therapy may occasionally result in symptomatic
- hypotension
- Application of the pattern of the pa

General. CARDIZEM (diltiazem hydrochloride) is extensively metab-General. CARDIZEM (diltazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and in bile. As with any new drug qiven over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In sub-acute and chronic dog and rat studies designed to produce toxicity, high dosse of diltazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, dosse of 20 mg/kg were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Drug Interaction. Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when using beta-blockers or digitalis concomitantly with CARDIZEM. (See WARNINGS)

WARNINGS

Tenderings: Controlled and uncontrolled domestic studies suggest that con-comitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, dilliazem has been shown to increase serum digoxin levels up to 20%

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity There was also no mutagenic response in in vitro bacterial tests. No in

Pregnancy. Category C. Reproduction studies have been con-ducted in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and letal lethality These doses, in some studies, have been reported to cause skeletal abnormalities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 2D times the human dose or greater

the numan dose or greater

There are no well-controlled studies in pregnant women, therefore, use CARDIZEM in pregnant women only if the potential benefit justifies the potential risk to the fetus

Nursing Mothers, it is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk. Because milk. B risks in this situation

Pediatric Use. Safety and effectiveness in children have not been established

#### **ADVERSE REACTIONS**

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been

excluded in domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that reported during placebo therapy. The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition in many cases, the relationship to CARDIZEM has not been established. The most common occurrences, a well as their foreigned of perspectives are adventiged. (2.63) as well as their frequency of presentation, are: edema (2.4%),

headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.3%), ashhenia (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence.

Cardiovascular Flushing, arrhythmia, hypotension, bradycar-

dia, palpitations, congestive heart failure,

syncope. Paresthesia, nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia. Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGDT, SGPT, and LDH. Pruritus, petechiae, urticaria, photosensitivity. Polyuria pocificia. Nervous System Gastrointestinal

Dermatologic

Polyuria, nocturia.

The following additional experiences have been noted. A patient with Prinzmetal's angina experiencing episodes of vasospastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of CARDIZEM.

The following postmarketing events have been reported infre-quently in patients receiving CARDIZEM; erythema multiforme; leu-kopenia; and extreme elevations of alkaline phosphatase, SGDT, SGPT, LDH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

#### **OVERDOSAGE OR EXAGGERATEO RESPONSE**

Overdosage experience with oral diltiazem has been limited. Simple oral doses of 300 mg of CARDIZEM have been well tolerated by heatthy volunteers. In the event of overdosage or exagger and response, appropriate supportive measures should be employed addition to gastric lavage. In the following measures may be considered addition to gastric lavage. In the following measures may be considered

Administer atropine (0.60 to 1.0 mg). If there 8radycardia

Administer adopting (0.00 to 7.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Treat as for bradycardia above. Fixed high-degree AV block should be treated with car-High-Degree AV

diac pacing.

Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics. Cardiac Failure Hypotension

Vasopressors (eg. dopamine or levarterenol bitartrate)

Actual treatment and dosage should depend on the severity of the clinical situation and the judgment and experience of the treating

physician. The oral/LD $_{\rm so}$ 's in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LD $_{\rm us}$ 's in these species were 60 and 38 mg/kg, respectively. The oral LD $_{\rm so}$  in dogs is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The toxic dose in man is not known, but blood levels in excess of 800 ng/ml have not been associated with noticity.

#### **OOSAGE AND ADMINISTRATION**

OOSAGE AND AOMINISTRATION

Exertional Angina Pectorie Due to Atherosclerotic Coronary Artery Disease or Angina Pectoria at Reat Due to Coronary Artery Spaem. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four times daily) at one: to two-day intervals until optimum response is obtained Although individual patients merspond to any dosage level, the average optimum dosage range appears to be 180 to 240 mg/day There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the drug must be used in such patients, titration should be carried out with particular caution.

function. If the drug must be used in such patients, titration should be carried out with particular caution.

Concomitant Use With Other Antlanginal Agents:

1. Sublingual NTG may be taken as required to abort acute anginal attacks during CARDIZEM therapy.

2. Prophylactic Nitrate Therapy — CARDIZEM may be safely cadministered with short- and long-acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination.

3 Beta-blockers. (See WARNINGS and PRECAUTIONS.)

#### HOW SUPPLIED

HOW SUPPLIED
Cardizem 30-mg lablets are supplied in bottles of 100 (NDC
0088-1771-47) and in Unit Dose Identification Paks of 100 (NDC
0088-1771-49), Each green tablet is engraved with MARIION on one
side and 1771 engraved on the other CARDIZEM 50-mg scored
tablets are supplied in bottles of 100 (NDC 0088-1772-47) and in Unit
Dose Identification Paks of 100 (NDC 0088-1772-49). Each yellow
tablet is engraved with MARION on one side and 1772 on the other Issued 4/1/84

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#### Using Focus Group Sessions Before Decisions Are Made

Leif C. Beck, LL.B., William L. Trombetta, Ph.D. and Scott Share

 Before you make extensive changes to your medical practice, and before you order expensive marketing research to test the water, try a focus group session.

SUPPOSE your solo or group practice is contemplating opening its own urgent care center. Suppose further that the urgent care center is tentatively planned to serve both as a convenience to your current patients and as a means of attracting new patients. Perhaps, however, the doctor-members are unsure how community residents would view the center, what types of services should be offered or even where the facility should be located. How should you proceed?

The doctor and his or her practice need substantive community feedback before planning this urgent care center. In-person, mail and/or telephone interviews of area residents would be the likely means of gathering this information. However, before embarking upon an expensive, time-consuming quantitative research endeavor, you might take advantage of another, relatively new, qualitative research technique — the focus group.

Regardless of the decision involved, whether a very major one like the urgi-center or a lesser one as to your office's planned expansion to evening or weekend hours, information as to likely community response — as developed in a focus group — could be invaluable to your process. Much time, money and potential embarassment could be saved if the response were reasonably predicted through a focus group undertaking.

#### Its Purpose

A focus group is, simply stated, an informal discussion among selected individuals about specific topics relevant to the situation at hand. Led by a group "leader," participants are encouraged to express their own views on certain topics, to elaborate on points and issues raised by others and generally to interact with group members. For instance, in the above-described situation, focus group participants might discuss the perceived advantages of an urgent care center over a private doctor's office (or a hospital emergency room), what services should be offered by such a center, their feelings of price and location sensitivity, estimated frequency of use and so forth.

#### Who Should Participate?

Focus group sessions normally consist of between six and ten individuals who have been carefully selected and invited to participate. A proper mix of community residents, professionals and business leaders should be represented, depending on the study's purpose. In our opening example, the focus group should be made up of typical area residents who make the health care decisions for their families. If the objectives were instead to obtain physician level input, then area physicians would obviously be solicited to participate.

Focus group participants are reimbursed for their time. The higher the individual's status, the greater is the incentive required. Homemakers, for instance, can usually be successfully recruited for \$20; business executives or other professionals might require payments of \$100 or more.

The most important participant in any focus group is the moderator. He or she should be skilled and experienced in leading focus sessions, usually having credentials in group psychology and dynamics. The moderator need not be a health care expert, but the hiring group must carefully instruct him or her as to the basic concepts to be discussed during the session.

#### The Format

The session should be held in a comfortable setting such as a hotel conference room — certainly not in the group's own building. The moderator would use a flexible agenda of subjects to structure the discussion, which usually lasts upwards of two hours.

Participants are normally not told who is sponsoring the research until the focus session has ended, if at all. This is to avoid injecting bias into their responses.

The sessions can be audio-taped or video-recorded for subsequent summary and analysis. Thus the medical group sponsoring the research can hear and/or see the session in action. If the sponsor insists on seeing the session live, the session should take place in a room equipped with a one-way mirror so the participants will not be distracted.

#### The Outcome

Individual focus participants will often appear to be

From The Health Care Group, One Belmout Avenue, Bala Cynwyd, PA 19004. Copyright by The Health Care Group, May 1985.

inaccurately informed about either the medical group, its products and services and/or the health care delivery system in general. This in itself may be a valuable finding. People's perceptions may be more important than the facts when public health care decisions are involved.

An analysis of the focus group discussion is obviously essential. The moderator will usually prepare a written report summarizing the session's objectives, the actual verbal interchanges between participants and the major points made, as well as his or her evaluation of the proceedings.

Along with reading the written report, it is often useful to view a videotape (if one exists) of the session. The ability to see and hear what actually transpired, including rerunning particularly important interchanges, is a major strength of the focus group technique. Spoken words sometimes take on different or additional meanings when facial expressions and tones are observed.

#### Advantages and Shortcomings

Focus groups offer potentially stimulating exchanges of ideas, thoughts and attitudes that may not erupt from personal interviews — the advantage of "brainstorming." These group discussions also offer more candor and spontaneity than may come from one-on-one interviews. Both of these advantages are attributable at least in part to the greater likelihood that people will speak out more when in the "safety" of a crowd.

There are also some disadvantages inherent in the focus group strategy. For one, focus group results cannot automatically be projected to the full community. Secondly, biases might, either intentionally or unintentionally, be built into the discussion or later findings by the participants, the moderator or even the management. There is also the risk that some "passive" participants will be unduly influenced or inhibited by the "active" participants. And one must also resist the temptation to treat the results as definitive findings, using them as a disproportionate basis for decision-making.

#### Use of Focus Group Information

The focus group findings should rarely, if ever, be the sole basis for your business decisions. This information

should instead help provide specific direction and substance for more qualitative survey instruments such as telephone, mail and/or personal interviews. Focus sessions will raise the issues upon which qualitative survey techniques will give you a data base from which to make intelligent program and service decisions, in addition to defining and refining your qualitative research technique which you or your practice might use to:

- develop your positions strategy (find out what people look for in a medical practice);
- test the acceptability and impact of promotional ideas;
- identify the source of public relations problems affecting your group or practice;
- identify your group's (and your competitor's) strengths and weaknesses;
- identify community residents' major and minor health needs; and
- obtain "grass roots" opinions on other topics that might be relevant to projects you might be planning.

#### Who Should Plan the Session?

While a practice's manager or administrator could conceivably plan, conduct and analyze the results of a focus group on his or her own, you would be much better served to hire an experienced firm to conduct the entire focus group process. This would include meeting with your representatives to discuss your goals and objectives, developing a session 'outline,' arranging for and conducting the session (including recruiting participants) and summarizing and analyzing the results.

The fee for "farming out" the entire process to an outside firm typically ranges from \$2,000 to \$3,000, depending on location, experience and the like. It is usually well worth the price — especially if a \$400,000 office or satellite facility, a \$60,000 new doctor employment, a costly marketing campaign or other expensive undertakings might be affected by the results.

Rather than risk being "off base" and uninformed about your community and its feelings about matters that affect your practice, you should seriously consider having a focus group session to better sharpen your decision-making process.

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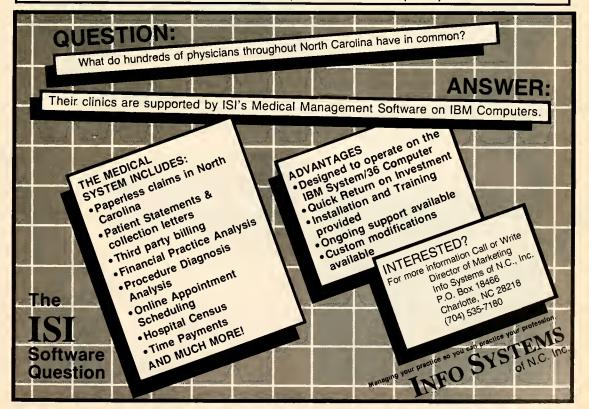
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#### North Carolina Medical Journal

#### Features for Patients

February 1986

#### Hospital Utilization in North Carolina: Three Years of Decline

Sandra B. Greene, Dr.P.H., and William J. DeMaria, M.D.

In 1983, Blue Cross and Blue Shield of North Carolina (BCBSNC) reported in this Journal on inpatient hospital utilization patterns in North Carolina. We presented 1981 data on admissions per 1,000 persons and days per 1,000 persons for both BCBSNC subscribers and Medicare beneficiaries by county of residence. and illustrated how these rates varied dramatically from one county to the next. We reviewed our finding that variations in utilization rates cannot be accounted for by socioeconomic factors or by patient and physician characteristics. We stated our belief that the variations are primarily associated with physician practice patterns. Cost implications of patterns of extensive hospital use are enormous. At that time, concerned employers recognized these facts and commenced including utilization data in designing and monitoring health insurance programs. We described how this was being done and reported our experience with the first preadmission certification program implemented in North Carolina.

In the interim, there has been an increase in both numbers and intensity of changes occurring in the

health care industry. The urgency to control cost increases has prompted fundamental alterations in the traditional methods of delivering and financing health care services.

This article is a follow-up of our earlier presentation of data to show how utilization rates have been affected as a consequence of the system changes. Our focus is on BCBSNC subscribers, with some additional comments about the Medicare population.

#### Utilization Changes, 1981-1984

Table 1 shows the utilization statistics for all BCBSNC subscribers in North Carolina for the four-year period 1981 through 1984. Over this interval, days/1,000 declined 25.5 percent, from 857.9 to 639.4 days/1,000, with the largest portion of this decline occurring during 1984. The drop in days can be attributed to a decrease in admissions as well as a

shortening of the length of stay. In comparing 1981 with 1984, the three-year decrease in admissions was 15.6 percent, while the average length of stay declined 11.7 percent.

Figure 1 shows the days/1,000 rate by county of residence for the BCBSNC population. Similar to data we reported in this Journal in 1983, utilization rates vary markedly from one county to the next. Also, as reported previously, we continue to believe that these variations are due primarily to differences in physician practice patterns. In 1981, Orange County was the only county exhibiting a rate under 500 days/1,000. Three years later (1984), there were six counties with rates this low: Camden, Chowan, Graham, Pamlico, Perquimans and Tyrrell. At the other end of the range, there were 12 counties in 1981 with days/1,000 above 1,000. Last year, there were only three counties with this high rate:

Table 1 Utilization Statistics for BCBSNC Subscribers, 1981-1984

	1981	1982	1983	1984
Admissions/1,000	129.3	127.1	121.4	109.1
Days/1,000	857.9	841.2	780.0	639.4
Average LOS	6.64	6.62	6.44	5.86

Fram Blue Cross and Blue Shield of North Carolina, Bax 2291, Durham 27702.

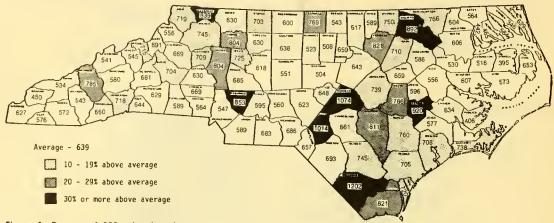


Figure 1. Days per 1,000 subscribers by county of residence, BCBSNC — 1984.

Columbus, Harnett and Hake counties.

Camparing statewide the 1984 county-specific day rates with the corresponding 1981 rotes, it is apparent that the decline in utilization was widespread. Figure 2 illustrates the percent change in days/1,000 over the three-year period. Ninety-faur of the State's 100 counties experienced same degree of utilization decline. Sixty-ane counties experienced dramatic declines of 20 percent or greater. Among these ore several counties that had the State's highest rates in 1981, including Avery, Richmond, Lincoln and Lenoir counties. Also included in this category,

though, are several counties such as Mecklenberg, Guilfard, Catowba and Cleveland which had what we believed in 1981 to be moderate rates. Twenty-seven counties experienced more moderate, although still impressive, declines of 10-19 percent. Six counties showed moderate decreases of less than 10 percent. Included in this group is Calumbus County which had the highest doys/1,000 rate in the State of 1,281 in 1981. It continues to have the highest rate with 1,202 doys/1,000 in 1984.

Orange County utilization increased moderately, from 484 to 508 days/1,000. Small increases were also seen in Allegheny, Caswell, Hor-

nett and Vance counties, while a substantial increase accurred in only Hoke County.

Diagnostic Specific Rates of Admissions

When a significant decline in utilization occurs, it is useful to discern if the drap can be attributed to selective types of diseases. Table 2 shows the days/1,000 rates by ICD-9 discharge classification, comparing rates for 1981 and 1984. Of the 17 categories, anly ane showed a significant increase: hospital discharges for mental disorders increased 31.7 percent. Discharges for infectious and parasitic diseases and pregnancy related conditions remained almost the

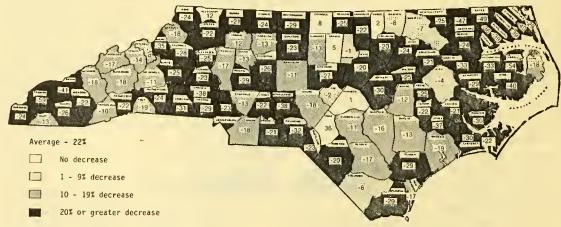


Figure 2. Percent change in days per 1,000 subscribers by county of residence from 1981 to 1984.

Table 2
Days Per 1,000 by ICD-9 Discharge Classification BCBSNC Subscribers, 1981-1984

		0	
			Percent
ICD-9 Discharge Classification	1981	1984	Change
Infectious and Parasitic Diseases	9.96	10.35	3.92
Neoplasms	64.40	55.41	-13.96
Endocrine, Nutritianal, and			
Metabolic Diseases	21.70	15.08	-30.51
Diseases of the Blaad	4.43	3.55	-19.86
Mentol Disarders	36.74	48.39	31.71
Diseases of the Nervous System	23.80	17.31	-27.27
Diseases of the Circulatory System	99.59	82.26	-17.40
Diseases of the Respiratory System	53.10	41.95	-21.00
Diseases of the Digestive System	96.50	75.36	-21.91
Diseases of the Genitaurinary			
System	81.58	58.79	-27.94
Pregnancy Related Canditions	57.26	59.02	3.07
Diseases of the Skin	11.08	7.89	- 28.79
Diseases of the Musculaskeletal			
System	55.92	46.40	- 17 02
Congenital Anomolies	6.08	5.44	-10.53
Certain Conditions Originating			
in the Perinatal Periad	12.10	9.40	-22.31
Symptoms, Signs, and III-Defined			
Conditions	54 14	40.34	-25.50

same, with very small increases. With the exception of these three categories, every other one showed a decline. No single disease type accounts for a major portion of the decline. Rather, the decrease appears to be consistent throughout most disease entities.

#### Medicare

From 1981 to 1984, the Medicare population also experienced a decline in utilization (table 3). This was in the order of a 16 percent decrease in days/1,000. The decrease was due almost entirely to a shortening in the average length of stay, from 10.19 days to 8.74 days. Admissions declined by only 1.6 percent during this time period.

#### Causes for the Decline in Utilization

Multiple factors have contributed to the rapid decline in utilization of inpatient hospital services during the past three years. For example, emplayers are trying various approaches to containing their insurance premiums. Included are benefit changes, separate add-on cost containment programs such as second opinion for surgery and preadmis-

sian certification. Many newly arganized coalitions are providing employers with the apportunity to examine data on utilization and costs, engaging in discussions with physicians and haspital administrators, and taking positions on certificate of need issues. These activities have stimulated an informed concern for health care costs among our major payors and their firm resolve to control their health care expenditures.

In addition to the emplayer and coalition activities, physicians have become more knowledgeable about the importance of their utilization patterns. They are increasingly sensitive to the overuse of costly inpatient services, as evidenced by selected changes in practice patterns.

These responses, in turn, have generated a remarkable change in

the delivery system. One of the most dramatic has been the development of large numbers of new and improved facilities for ambulatory diagnostics and surgery. In addition, home health care services have proliferated as an alternative to continued inpatient care.

Due to the fact that there are multiple forces interacting to produce the decline, it is difficult to identify the effects of any individual factor. We can, however, describe the utilization decline by measuring some of these factors individually.

#### Ambulatory Surgery

Far several years, BCBSNC has been intensively pramoting the use of autpatient surgery as a cast cantainment measure. We have reported our pragress with this praject in prior issues of the Journal. 2, 3 For monitoring purposes, we use a group of surgical pracedures deemed appropriate to be performed in an ambulatary setting. These include D&C, tubal ligation, arthroscopy, and endoscopy. In 1981, 34.7 percent of these procedures were performed in ambulatary settings. In 1984, that percentage grew to 61.5 percent. There are naw only five counties in North Caralina where aur monitared procedures are performed an an outpatient basis less than 40 percent of the time. Although variations in use of ambulatory surgery still exist, it is clear that it is now widely available.

The predominant location for ambulatory surgery in North Carolina is in haspital settings. During the past three years, however, there has been an emergence of a new category of provider, the freestanding ambulatory surgery facility. At the

Table 3
Utilization Statistics for Medicare Beneficiaries, 1981-1984

	1981	1982	1983	1984
Admissians/1,000	306.0	325.2	325.8	301.1
Days/1,000	3,262.0	3,470.6	3,324.0	2,731.5
Average LOS	10.19	10.19	9.65	8.74

end af 1984, Certificates of Need had been granted to 35 facilities af which 28 were already in operation.

#### Office Surgery

In 1982, BCBSNC begon an Office Surgery Incentive Pragram to encourage physicians to perform procedures in the least castly setting, the doctor's affice. Additional benefits of up to 25 percent of the usual, customary and reasonable allowance for a selected group of 88 pracedures were offered when the office setting was chosen. In 1981, prior to the pilat project, 21.4 percent of the 88 procedures were performed in affice settings for BCBSNC subscribers. In 1984, the correspanding percentage had increased to 29.2 percent. With this degree of improvement, the pilat program was cansidered successful. The pragram has since been expanded to include additional pracedures and is an ongoing Plon cast containment program.

#### Coinsurance/Deductibles

Priar to 1981, the predaminant coverage affered by BCBSNC featured first dollar benefits far inpatient coverage. In respanse ta market demand, in 1981, BCBSNC initiated coverage with coinsurance and deductibles, referred ta as Comprehensive Majar Medical (CMM). It was not until 1982, however, that CMM became popular with employers. By the end of 1984, nearly 52 percent of BCBSNC business had this coverage.

The trend in North Caralina taward benefits with cast sharing features mirrors the shift that has been seen nationally. In a recent survey of 1,185 employers nationwide, Hewitt Associates found that 63 percent of the employers include deductibles in their caverage, and 43 percent require cainsurance. These percentages have increased rapidly since 1982.4

In 1984, BCBSNC completed a study on the effects of CMM coverage. We examined utilization of hospital services in 40 large groups that changed fram first dallar coverage to CMM during 1981 and 1982. The

level af cost sharing in these graups was a \$100 deductible and 80/20 cainsurance. In the year after the benefit change, the 40 groups collectively experienced a 14 percent decrease in days/1,000 in controst to a 3 percent decline among control graups. In spite af the decline, the 40 groups' experience remained higher than the contrals, indicating these graups were unusual with respect to their utilization rates. Nevertheless, CMM coverage did result in a decline in the use af inpatient services.

#### Preadmission Certification

BCBSNC implemented the first preadmissian review program (PAC) in North Caralino in 1983. Designed ta reduce inapprapriate use of inpatient services, this pragram requires priar approval for reimbursement far all nanemergency and nanmaternity admissians. The purpose of the pragram is to encourage the use af ambulatary surgery and autpatient diagnostic testing and to discourage weekend admissions. The program was initiated in a textile plant in the western port of North Caralina in January 1983. Details of the program have been reparted previously.1

Since the introduction of PAC, the textile group has experienced dromatic reductions in utilization. During 1983, days/1,000 decreased 36 percent, from 1,009 to 645 days/ 1,000. The admission rate declined 29 percent, while the use of ambulotary surgery for a graup of manitored pracedures increased 147 percent. The battam line sovings to the employer and employees of this group was opproximately \$545,000 an a benefit program of \$1.6 million. While the group had also made some benefit changes and intraduced o preferred haspital orrangement at the same time as the PAC program, it is prabable that the PAC program hod the greatest impact. During 1984, the graup's second year an PAC, another significant drop in utilizotion was evident, Days/1,000 declined 26 percent aver 1983 while the admission rate decreased 16 percent.

Consequently, over a two-year period on PAC, the graup has experienced a 53 percent decline in days/ 1,000 and a 40 percent decline in the admission rate. The average length of stay for the graup's admissions dropped by 21 percent during the two-year period.

Althaugh BCBSNC did nat begin to market the PAC program widely until 1985, several groups were permitted ta implement it in 1984. By December 1984, 55 graups, camprising 52,000 porticipants, were on PAC. It is nat anticipated that mast groups will experience the magnitude of utilization declines as did the first graup since that one, initially, had on unusually high rate of utilization. Preliminary results from the groups that joined in 1984 indicate that utilization (days/1,000) is drapping by 15-20 percent on an annual basis.

#### Diagnastic Related Graups (DRGs)

Beginning in October 1983, the Health Care Financing Administration intraduced a new method of reimbursing far Medicare hospitalizations, a flot fee based an diagnasis. For most haspitals in North Carolina, this went into effect in Octaber 1983 or July 1984. Utilization of inpatient services has subsequently declined nationally and in North Caralino far both the Medicare papulatian as well as other patients. This decline has been attributed, to a great extent, ta the DRG method of payment and the resulting changes in physician practice patterns.

Although BCBSNC does nat use the DRG reimbursement methad, it is likely that there is a spillover effect. Physicians have perhaps altered their practice patterns to some extent for all patients they treat rather than singling out the Medicare population. Thus, it is likely that the new method af Medicare reimbursement has been a factor in the declining BCBSNC utilization.

#### What We Expect for the Future

In view af a myriad af health care system changes, it is mare likely that

utilizatian will cantinue ta decline far a periad of time. A number of factars lead us to this conclusian:

- At the end af 1984, 52 percent of BCBSNC subscribers had coverage with cost sharing features. Many af the groups accounting far the remaining 48 percent of the subscribers will change to cost sharing features in the next few years. For thase groups olready purchasing coinsurance and deductible coverage, there is a tendency to increase the amount of cast sharing when their cantract is renewed. Bath af these activities, more graups chonging ta CMM caverage and a movement to increase the amount of cost sharing benefits with CMM. will likely result in a further decrease in inpatient utilization in the BCBSNC papulation.
- Preadmission certification is the single mast effective pragram for controlling unnecessary utilization. Yet the decline in hospital days seen through 1984 preceded any impact of this program. At the end af 1984, anly 4 percent of BCBSNC participants were on PAC, and most of them joined the program late in 1984. By the end of 1985, we anticipate that 37 percent (500,000 subscribers) af our enrallment will be participating, increasing to 70-80 percent by 1986 year-end. Clearly the major impact of this pragram an inpatient use will be experienced initially in 1985 and 1986.
- During 1982-1984, there wos an increase in the availability of facilities and services far the pravisian of outpatient care. This increase is accelerating in 1985 in the farm of home health agencies, birthing centers, hospital based ambulatary centers, freestanding ambulatary surgery centers, freestanding dialysis centers, and urgent care centers as well as the more traditional hospital based autpatient treatment centers. This will lead to a further shift over the next few years

in the lacation where services are delivered, by maving mare surgery and diagnostic testing aut of the inpatient setting.

- Although it is widely believed that the Medicare DRG reimbursement pragram has already had an impact on utilization, we recagnize that this pragram is not yet fully in place. As the reimbursement maves to national rates, rather than rates based heavily an local charges, it may further influence physician practice styles. To the extent that the change in practice styles results in reduced inpatient care for the Medicare population, a similar impact on the nan-Medicare population con be anticipated.
- At the end of 1984, the Peer Review Organization (PRO) in North Carolina was in on organizational state. Cansequently, 1984 utilization rotes do not reflect the impact of this potentially powerful program. PROs have a mandate to perform pre and postadmission reviews for medical necessity, quality of care, and the appropriateness of the level of core. When these functions are fully in place, it is likely to have a further impact on the way medical services are delivered in North Carolina.
- The Health Maintenance Organization (HMO) movement in North Caralina is naw gaining strength but, during the 1981-1984 time periad, only a small number of North Carolinians were in these programs. HMOs are designed to monitar and cantral utilization by minimizing the use of inpatient care. It is widely believed that a rapidly growing propartian of the papulatian will jain such programs aver the next few years. To the extent this proves true, o further drop in utilization can be anticipated.
- During 1982-1984, there were many business/medicine coolitions farmed throughout the State. Their impact an utilization during that

time period was probably minimal due to the newness of their organizations. We are now beginning to see same of these mature. A few are selecting programs to implement that ore designed to have an impact an haspital utilization.

Each of these pragrams will have an impact an utilization patterns, especially as they pertain to shortterm gaals of cost containment. For the lang-term process, however, ta maintain brakes an the inappropriate utilization of medical services, we believe one effort laams as most important: that is, the increased awareness and direct involvement of business and industry leaders in making decisions regarding the health care programs of their respective companies. Company executives ore accessing pertinent information an their health care insurance pragrams, primarily through their insurance corriers. This information consists of data an utilization and cast patterns related to how their employees use medical care services. With such infarmation, they are in on aptimal positian to select pragrams far controlling canfirmed averuse and misuse of the health care system. This allaws them, as primary payors of medical care, the apportunity for cost effective monagement of their health core benefit programs without compromising the quality of care. We see this effort becoming both mare widespread and intense as emplayers gain mare expertise in requesting pertinent data and interpreting its significance and consequently ossuming full responsibility for cantralling their health care expenditures.

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#### School and the Medically Handicapped Child

Patricia B. Porter, Ph.D., Thomas H. Cameron, Ph.D., and Colin D. Hall, M.B., Ch.B.

At school, children not only learn the fundamental skills that will enable them to campete in adult society, they olso learn social skills that will allow them to coexist with other adults and thus increase the richness of their lives. Remember that the medically handicapped child spends many hours in school. Communication among doctors, teachers and parents is important. It is porticularly impartant that the school experience be a good one for the handicapped child.

Many of the children we see will be unable to have a career that is at all physically demanding. To have any chance of becoming financially independent they must have the best possible educational training to prepare them for the job morket. Some children will not survive ta complete school. They will often be severely restricted in their ability to move outside the home, and school may be the anly place where they can make friendships and enjoy the richness of human cantact outside the immediate family. In a life where physical abilities are cantinually regressing, school may be the only setting where they can experience the sense of achievement that is essential to emotional development. All those involved must strive to make this as positive an experience os possible.

We found that four out of five of the children attending our neuromuscular clinic had classraam problems related to their diseases. The problems and their solution remained unaddressed because of lack of communication between school person-

nel, health persannel and parents. We established a way to communicate among these three areas. The results have been very rewarding. The system is adaptable to all clinical settings and is probably relevant to all children of school age attending medical clinics for chranic diseases. Experienced educators served as the primary clinic/school/parent liaisons in our neuromuscular team, but in situatians where this is not possible the physician, nurse, social worker, accupational or physical therapist can carry out a similar rale.

Cammunication occurs in the follawing way. The health team from our clinic abtoins information about the school situation. They contact the teacher by phane, by writing ar by personal interview and compore the teacher's perception of the child's school experience with that of the child and parents. The teachers are usually delighted with our interest. We follow this contact with written moterial on the disease, its course and prognosis and the commonly accurring problems created by the illness. Follow-up showed that the school experience is hoppier and more intellectually rewarding.

It is not possible to describe each individual difficulty we encauntered. Nor would it be very helpful, because each child is unique and the lesson we have learned is that it is important to listen to each stary and individualize each solution. However, it may be useful to document some af the more commonly occurring themes and solutions.

Teachers did not know to what extent they should discuss the disease with the children ar their parents. They did nat know to whot extent they should "protect" the children by nat mentioning their handicaps. We infarmed the teochers of what had been explained to the families, and provided them with copies of the letters we send to the fomilies after each clinic visit. The letters to the family reinforce what we tell potients, and we feel that both the patient and the fomily have a right and a need to quite detailed information about their condition.

Issues of "special favor" or "laoking stronge" that were vaiced by classroam peers or that led to negative acting out by these peers was helped by encouroging frank discussion in a classroom setting, while protecting the sensitivity of the affected individual. Often getting classmates to help in alleviating problems, such as carrying baoks or pushing wheelchairs, could be very rewarding.

Transportation to and from school was helped by recruiting an older child to help the patient get on and aff the school bus or by arranging to have a van that is specially odapted for physically disabled children pick up and deliver the child.

Access within the school itself was often a problem. At times classrooms could be moved from upstairs to downstairs. Tailet access could be helped by providing an aide of the appropriate sex to help with this on a regular basis. This person was usually another teacher, an aide, or a member of the janitorial service. At times, structural alterations in the bathrooms were required to moke them wheelchair accessible.

Expectations of childrens' academic abilities were often limited by both teachers and parents in situations where the problems were entirely physical. In other situations, it was not realized that poor academic

Fram the Division far Disarders of Development and Learning and the Neuromuscular Unit, Department of Neuralogy, University of North Carolina School of Medicine, Chapel Hill 27514

perfarmance, bath in the classraom and on standardized tests, resulted fram fatigue or clumsiness due to physical problems. In these situatians, readjustment of goals was helpful.

Acting aut behavior in closs had aften been permitted because the teacher was unwilling to set the same disciplinary standards for a hondicopped child os far other children in the class. When the teacher understand that it was acceptable and in-

deed beneficial to set limits on the handicapped child's behavior, the difficulties could be greatly reduced.

Medical equipment such as locking leg broces created problems, but explanation of their mechanism and encouragement of the teacher to help with them was usually all that was required to alleviate these problems. The same was true of medications that had to be taken during school hours.

Ways could aften be faund to sup-

plement functional ability by adapting writing equipment, desks or wheelchair accessories, using typewriters or tape recarders. Teachers were often willing tamodify their testing pracedures to ollow more time ance the child's problems were explained to them.

We believe the method of communication described in this paper is applicable to all children with chronic illness. We hope you will try our plan and let us know of your results.

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The addition of a diuretic enhances the efficacy of the beta-blocker.

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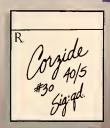
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\*Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure.

The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 144:1045-1057, 1984.

Please see brief summary of prescribing information on following page

# CORZIDE

(nadolol-bendroflumethiazide tablets)

CORZIDE® 40/5 Nadolol-Bendroflumethiazide Tablets

DESCRIPTION: CORZIDE (Nadolol-Bendroflumethiazide Tablets) for oral administration combines two antihypertensive agents. CORGARD® (nadolol), a nonselective beta-adrener-gic blocking agent, and NATURETIN® (bendroflumethiazide), a thiazide diuretic-antihyperiensive. Formulations: 40 mg and 80 mg nadolol per lablet combined with 5 mg bendroflumethiazide

CONTRAINDICATIONS: Nedolol — Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS). Beandroflumethiazide — Anuria, and in those with previous hypersensitivity to bendroflu-methiazide or other sulfonamide-derived drugs

methiazade or other sulfonamide-derived drugs

WARNINGS: Nadolol — Cardiac Failura — Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockets should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of Italiure who are well compensated, usually with digitals and disuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, digitalize and/or give disretics, and closely observe response, or discontinue nadolol (gradually, if possible).

Execerbation of Ischemic Heart Disease Following Abrupt Withdrawal — Hypersensitivity to catecholamines has been observed in patients withdrawn from beta blocker therapy, exacerbation of angina and, in some cases, myocardial infarction have occurred after abrupt discontinuation of such therapy. When discontinuing chronic use of nadolo, particularly in patients with ischemic heart disease, gradually reduce dosage over a 1- to 2 week period and carefully monitor the patient. Reinstitute nadolo promptly (at least temporarily) and take other measures appropriate for management of unstable anging if angina markedly worsens or acute coronary insufficiency develops. Warn patients not to interrupt or discontinue therapy without physician's advice. Because coronary artery disease is common and may be unrecognized, it may be prudent not to discontinue nadolol therapy abruptly even in patients treated only for hypertension.

Abruptly even in patients treated only for hypertension

Nonallergic Bronchospasm (e.g., chronic bronchitis, emphysema) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolol with caution since it may block bronchodilation produced by endogenous or exogenous catecholamine stimulation of beta, receiptors. Major Surgery — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase the risks of general anaesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, it has generally been suggested that such therapy should be withdrawn several days prior to surgery. Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place, in amergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as responsivened, dopamine, dobutamine, or levarterenoi can reverse the effects of nadolol. Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic tockade may prevent the appearance of premonitory signs and symptoms (e.g., tachycardia and blood pressure changes) of acute hypoglycemia. This is especially important with fable diabetics. Beta-blockade also reduces release of insulin in response to hyperglycemia, therefore, it may be necessary to adjust dose of antidiabetic drugs Thyrotoxicosis.— Beta-adrenergic blockade may mask certain clinical signs (e.g., tachycardia) of hyperthyroidism. To avoid abrupt withdrawal of beta-adrenergic blockade which might precipitate a thyroid storm, carefully manage patients suspected of developing thyrotoxicosis.

Bandroflumethlazide — Use with caution in severe renal disease. In patients with renal disease, azotemia may be precipitated. With impaired renal function, effects of the drug may be cumulative. Use with caution in impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Sensitivity reactions may occur in patients with a history of allergy or bronchial asthma. Possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

**PRECAUTIONS: General — Nadolol —** Use with caution in patients with impaired hepatic or renal function (see DOSAGE AND ADMINISTRATION).

or renal function (see DOSAGE AND ADMINISTRATION).

Bandrollumathiezide — At appropriate intervals, perform serum electrolytes determination to detect possible electrolyte imbalance warning signs of which are dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular tatique, hypotension, oliquiria, tachycardia, and G.I. disturbances such as nausea and vomiting Observe patients for clinical signs of fluid or electrolyte imbalance, namely, hyponatermia, hypochloremic alkalosis, hypokalemia Serum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Drugs such as digitals may influence serum electrolytes Hypokalema may develop, especially with brisk diuresis, in presence of severe cirrhosis Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Response of the heart to toxic effects of digitals can be exaggerated with hypokalemia. Desponses of the heart to toxic effects of digitals can be exaggerated with hypokalemia. We poliassium supplements such as high potassium floods to avoid or treat hypokalemia. Any chloride deficit is generally mild and usually does not require specific therapy except under extraordinary circumstances (as in liver or renal desease). Diuthonal hyponatermia may occur in edematious patients in hot weather, appropriate therapy is water restriction rather than salt administration except in rare instances when the hypopartermans life threatening in actual salt definishments.

when he hyponatremia is life threatening. In actual salt depletion, appropriate reproductions the therepy of choice.

Hyperuricemia may occur or frank gout may be precipitated in certain thiazide-treated patients. Latent diabetes mellitus may become maintest during liniazide therapy. Antihyperiensive effects of bendrofulmethiazide may be enhanced in the postsympathectomy patient. Careful reappraisal of therapy and consideration given to withholding or stopping duretic therapy is necessary if insign opropriotin nitrogen or BUN (indicative of progressive renal impairment) occurs. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Thiazides decrease calcium excetion. Pathologic changes in parathyroid gland with hypercalcemia and hypophosphatemia have been occasionally observed with prolonged therapy. Common complications of hyperparathyroidism have not been seen.

Information for Patients — Warn patients, especially those with evidence of coronary artery insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiact failure ariety occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at the first sign or symptom of impending failure. Advise patients of proper course if dose inadvertently missed.

of impending failure. Advise palients of proper course if dose inadvertently missed.

Lehoratory Tests.— Regularly monitor serum and urine electrolyte levels (see WARNINGS, Bendroflumethiazide, and PRECAUTIONS, General, Bendroflumethiazide).

Drug Intaractions.— Nadoloi.— When administered concurrently the following drugs may interact with beta-adrenergic blocking agents. Anasthelics, ganeral.— exaggeration of anesthetic-induced hypotension (see WARNINGS, Nadoloi, Major Surgery). Antidiabetic drugs (oral agents and insulin).— hypotypermia or hyperglycemia, adjust antidiabetic drug dosage accordingly (see WARNINGS, Nadoloi, Diabetes and Hypoglycemia). Catechol-amina-depleting drugs (e.g., reserpine).— additive effect, monitor closely for evidence of hypotension and/or excessive bradycardia.

Bandroffumethiazide.— When administered concurrently the fellowing drugs are accurately.

hypotension and/or excessive bradycardia

Bandroflumethiazide — When administered concurrently the following drugs may interact with thiazide duretics. Alcohol, barbifuretes, or narcotics — may potentiate orthostatic hypotension. Antidiabetic drugs (oral agents and insulin) — thiazide-induced hypotension. Antidiabetic drugs (oral agents and insulin) — thiazide-induced hypotension arequire adjustment of antidiabetic drug dosage. Other antihypoetansive drugs — additive or potentiated effect. Corticosteroide, ACTH — intensified electrolyte depletion, particularly hypodalemia Ganglionic or peripharal adranagic blocking drugs — potentiated diffect. Preanesthetic and anesthatic agents — effects may be potentiated, adjust dosage accordingly Pressor amines (e.g., noreplinephrine) — possible decrease response but not sufficient to preclude their use Skeletal muscle relaxants, nondepolar-lizing (e.g., tubocurarine) — possible micrased response.

Drug/Laboratory Test interactions — Discontinue thiazides before tests for parathyroid function (see PRECAUTIONS, General, Bendroflumethiazide).

Carcinogenesis, Mutagenesis, Impairment of Fertillity — Nadolol — In 1 to 2 years oral toxicologic studies in mice, rats, and dogs, nadolol did not produce eignificant toxic effects. In 2-year oral carcinogenic studies in rats and mice, nadolol did not produce neoplastic, preneoplastic, or nonneoplastic pathologic lessons. Bendroflumathiazide — Long-term studies in animals have not been performed

Pregnency — Teratogenic Effects — Nadolol — Category C. In animal reproduction

animals have not been performed 
Pregnency — Teratogenic Effects — Nadolol — Category C. In animal reproduction 
studies with nadolol, evidence of embryo- and felotoxicity was found in rabbits, but not in rats 
or hamsters, at doses 5 to 10 times greater (on a mg/kg basis) than the maximum indicated 
human dose, no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women, therefore, use nadolol in pregnant women only if potential 
benefit justifies potential risk to the fetus. Bandrollumethiazide — Category C. Animal 
reproduction studies have not been conducted. This drug's effect on the fetus when administered to a pregnant women or its effect on reproductive capacity is not known. Bendrollumethiazide should be given to a pregnant woman only if clearly needed. Nonteratogenic 
Effects — Since thiazides cross the placental barrier and appear in cord blood, weigh anticipaled benefit of the drug in pregnant women against possible hazards to the fetus, these 
hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other reactions 
which have occurred in adults. which have occurred in adults.

Nursing Mothers — Both nadolol and bendroflumethiazide are excreted in human milk. Because of the potential for serious adverse reactions in nursing infants either discontinue nursing or discontinue therapy, taking into account the importance of CORZIDE (Nadolol-Bendroflumethiazide Tablets) to the mother. Pedilatric Use — Sately and effectiveness in children have not been established

Bendroflumethiazide Tablets) to the mother.

Pediatric Usa — Sately and effectiveness in children have not been established

ADVERSE REACTIONS: Nacioloi — Most adverse effects have been mild and transient and have rarely required nacioloi withdrawal. Cardiovascular — Bradycardia with heart rates of less than 60 beautisper more commonly, and heart rates believe to beats per minde and transient and provided the provided of the provided and transient and an

erythematous rash, arterial insufficiency

Bendrollumethiazide — Gastrointastinal System — anorexia, gastric irritation, nausea, vomiting, cramping, darrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatitis Central Nervous System — dizzinass, vertigo, paresthesia, headache, xanthopsia Hematologic — leukopenia, agianulocytosis, thrombocytopenia, aplastic anemia Dermatologic-Hypersenstitivity — purpura, photosensitivity, rash, urticaria, necrotizing angilis (vasculitis, cultaneous vasculitis). Cardiovascular — orthostatic hypotension may occur. Other — hyperglycemia, glycosuria, occasional metabolic acidosis in diabetics, hyperuncemia, allegic glomerulonephritis, muscle spasm, weakness, restlessness Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn. withdrawn

withdrawn.

OVERDOSAGE: Nadolol may cause excessive bradycardia, cardiac failure, hypotension, or bronchospasm il overdosed. Overdosage of thiazides may cause lethargy, which may progress to coma within a lew hours, with minimal depression of respiration and cardiovascular function and without evidence of serum electrolyte changes or dehydration. Gastrointestinal irritation and hypermotility may occur. Transitory increase in BUN and serum electrolyte changes may occur, especially in patients with real impairment.

Treatment — Nadolol can be removed from the general circulation by hemodialysis. In determining duration of corrective therapy, take note of the long duration of the effect of nadolol in addition to gastric lavage, employ the following measures, as appropriate Excessive Bradycardia — Administer actionne (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproferenol cautiously. Cardiac Fallure — Administer a digitalis glycoside and diurelic. It has been reported that glucagon may also be useful in this situation. Hypotension — Administer visoprossoris, e.g., epinephrine or levarterenol. (There is evidence that epinephrine may be the dug of choice.) Bronchospes — Administer a beta; stimulating agent and/or a theophylline derivative Stupor or Come — Supportive therapy as warranted. Gastrointestinal Effects.— Symptomatic treatment as needed BUN and/or Serum Electrolyte Abnormalities — institute supportive measures as required to maintain hydration, electrolyte balance, respiration, and cardiovascular and renal function.

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with renal failure require adjustment in dosing interval, see package insert for dosage in these

Consult package insert before prescribing CORZIDE (Nadolol-Bendroflumethiazide

HOW SUPPLIED: Available as scored tablets containing 40 mg nadolol combined with 5 mg ben droflumethiazide and 80 mg nadolol combined with 5 mg bendroflumethiazide in bottles of 100

## The Aging Physician and Current Medical Practice

James H. Sanders, Jr., M.D.

• A guide for experienced physicians practicing in the eighties.

IF you are an older physician on the cutting edge of medical scientific investigation, practice or politics, don't bother reading this. It doesn't concern you. If, however, you are one of the majority who has tried to practice good medicine for years, finds himself a senior physician, and is somewhat overwhelmed with the changes taking place in medical practice, then these are some factors you should carefully consider.

With the demands of modern practice, the days are over for the doctor on call 24 hours a day, seven days a week. The main attraction of group practice is time from work for normal family life. Even solo physicians have nearly all worked out some type of call arrangement with other physicians. Many older physicians have not made extensive call arrangements and are still on call most of the time. Because they need more time off they may not respond quickly to some calls and if it doesn't sound urgent, not at all. With the splintering of medicine into more and more subspecialties and with the increasing number of physicians, there is the tendency to say, "Let George do it." We must take care of the problems of our own patients. The point is - you do it or you don't. We must be on call or off. We must see that our patients can get the care they need all the time, either from us or by definite arrangement with other physicians.

Some, especially older physicians, leave the call situation vague so that the hospital, their offices, their families and their patients don't know whom to call. Most cling to the ideal of the patient's personal physician for whom the patient's loyalty is so strong that except for dire emergencies, he will wait until the "great one" can be seen. That ideal was never as prevalent as physicians thought and it is almost dead now. What patients want is fast, convenient care whenever they want it. As the cost of medical care skyrockets, government, industry and insurance companies fight for cost containment. Most patients think about this, if they do at all, only after they get the bills. The personal physician who knows the patient is always admired as the ideal in polls but is probably the last in the list of requirements when people get sick. The fear that patients may switch allegiance keeps many from working out good call arrangements. This loses more patients when the doctor is hard to find or reluctant to come.

Another problem is that older physicians often don't

investigate and treat as aggressively as present practice dictates. Many tests and procedures have been developed since we started practice. If we are not familiar with them, we tend to feel that they are unnecessary. Didn't our patients do OK without them and with less trouble and cost? And doesn't every wise physician agree that American patients are getting too many tests, treatments and operations? Maybe so; but how many physicians do you know who have lost their hospital privileges for ordering too many tests and treatment procedures? We all get penalized if we don't get enough, fast enough. Even our patients are punished if we don't use expensive tests and procedures. Under diagnosis related groups (DRGs), a Medicare patient with pneumonia will have payments for hospital care denied if you don't get blood gas determinations or give intravenous antibiotics. Other factors may have determined the need for hospital admission but try to explain that to the peer review organization.

Remember that just as the young physician starting out, the older physician is under the spotlight. The young doctor quickly becomes part of "the establishment" (unless he is a maverick or peculiar); but the spotlight gets brighter on the older physician the older he or she gets — and with good reason. Some physicians do cling to outmoded practices. Some do develop mental and physical disabilities that

should prevent continued practice.

What must we older physicians do to see that our patients

get proper care and protect ourselves?

1. Don't rest on your laurels. In practicing medicine, it is not what you have done but what you are doing that counts. It is fine that you are certified in your specialty, that you are a fellow in this or that and that you have been president of something or other. Just remember, that is for what you have done in the past. Your patients don't benefit from your past accomplishments. Even reading, studying, attending meetings and taking recertification exams aren't enough. Patients benefit from our knowledge and skill only if they are properly applied.

2. Keep up your clinical records! The whole world now runs on records. When I started, medical records showed that something was found and something was done. Now you must record everything found and not found, and everything done and how, and not done and why. You won't get any awards or appreciation for readability, conciseness, completeness or timeliness, but the chances of

getting hung for not producing adequate records are increasing daily.

3. Ask for consultations or refer the patient when appropriate. I know our generation came into medicine feeling we were renaissance physicians, competent to treat anything and everything. This isn't true now and we damage patients and ourselves when we treat problems others are more competent to handle. Be careful, however, not to let consultants take over the care of your patients in the hospital, if you continue to keep them on your service. That causes confusion for everyone. If you feel that someone else should take care of the patient, turn him or her over to another physician. If you keep the patient, you also keep the responsibility for directing care provided.

4. Use the latest accepted tests and treatments. In some cases they may be unnecessary and not cost effective, but unless you have the evidence and document it in the chart, you had better do what is currently accepted. Not long ago eminent physicians were scoffing at "cookbook medicine." Well, that is what we have now. It is a loose-leaf cookbook with ever-increasing changes in the recipes.

5. Be available when you are on call and go when you are called. It is reasonable to take more time off than you used to but you must see that care is available for your patients when you aren't. You can't be partially on call or on call just for those you want to see.

6. Limit your practice to what you really know and like. Everyone is a specialist these days. Most of us are subspecialists to some degree even if we don't advertise the fact.

7. Use caution with addictive drugs and prescribe small quantities for only short periods. As medical director of a chemical dependency unit, I see a disturbing number of addicts produced by physicians. Do not prescribe any addictive drug to an alcoholic or drug addict except for detoxification or for acute conditions treated in a hospital. If you do not know about cross addiction, you better learn

fast. The Valium you give a sober alcoholic may start him drinking again. Many older physicians are known suckers for writing addictive drug prescriptions. Ignorance and carelessness in the prescription of addictive drugs are widespread. Most states have increased surveillance of this problem. Don't be a fool.

8. Don't hang on to medical organization power and position purely to boost your ego or to keep things as they are. You will lose your position with bitterness and you cannot prevent change.

9. Don't get caught in the trap of accepting and then advocating some treatment that is purported to be good for nearly everything. Older physicians are more likely to get caught in this, perhaps because we, like our patients, desperately want a simple solution to many unsolved medical problems. Many, including some renowned physicians, have drifted to the fringes of medicine and some have dropped off the edge with such practices.

Much is being done in finding and rehabilitating the impaired physician — the one with alcohol or other drug dependence or mental illness. We haven't done much to help the physician who fails to meet his obligations because of obsolete practices. Problems are usually allowed to deteriorate to the point where rehabilitation is difficult. Medicine selected bull-headed individuals for its ranks in the past. The task of forcing us to change with the times isn't easy, but it must be done.

There is a bright side to this picture. Don't worry about becoming the "old doctor." Aging has not yet been declared a felony and patients think we look wise even if we are not. Don't fret about appearing old fashioned. Fashion is a matter of taste and, like old neck ties or dresses, if you hang around long enough you will be back in style. Prevention is the best medicine. Work hard to practice current medicine. We can't prevent ourselves from becoming old doctors, but we don't have to become obsolete old doctors.

#### The Funding of Graduate Medical Education

Frank C. Wilson, M.D.

 After four years of medical school, where does the newly-minted physician go for support during the remaining years of training?

DURING the past few years, the financial environment of teaching hospitals has become increasingly threatened by the unique costs to these institutions for graduate medical education, charity and tertiary care, and the development of new technology. These additional costs have spiraled to about \$3 billion per year in the Medicare budget alone. Therefore, a number of hospital payors, Medicare in particular, are reevaluating their practice of including funds for anything beyond patient care. When it is realized that over 50 percent of the 75,000 or so residents in the United States are being educated in only 2 percent (125) of the nation's hospitals, the particular relevance of this problem for teaching hospitals becomes obvious.

With the institution of the diagnosis related group (DRG) prospective payment system in 1983, Medicare recognized these added costs to teaching hospitals by agreeing to pay direct costs (resident salaries) on a reasonable cost basis (\$1 billion annually); they also added an indirect payment (\$2 billion annually) to compensate for the increased expenses to teaching hospitals accruing from a more severe problem mix and more indigent care. This indirect supplement was set at 11.59 percent of the prospectively set DRG price for each 0.1 resident per bed.

Needless to say, these hospitals were alarmed by President Reagan's budget proposal for 1986, which would freeze direct payments at the 1985 level and cut the indirect add-on percentage in half.

Further reduction in the funds available for graduate medical eduction may be anticipated from a decline in the use of hospital facilities, a trend that will probably continue with the development of health maintenance organizations. A related side effect is the greater reluctance of for-profit institutions to admit indigent patients, which may add even more to the financial burden on teaching hospitals.

There are basically two ways to solve this funding problem. One is to cut expenses, which may be accomplished by reducing (a) resident salaries, (b) the number of residents, or (c) the number of years funded for each resident. The other alternative is to find more money which, given the pressures to reduce the costs of medical care, has not found many sympathetic ears. Not surprisingly then, the focus has been on reducing costs, which has its own set of problems and societal issues.

The first option, that of reducing resident salaries, has received surprisingly little attention. During the past 25 years, the average resident stipend has increased from

about \$1500 per year to \$25,000 per year, i.e., by a factor of 16 or 17. Some dinosaurs remember making \$10 a month as an intern; and while few would advocate a return to such spartan conditions, it is probably safe to say that salary increases for house officers will be more modest than in the past.

Reducing the number of residents has, on the other hand, received considerable scrutiny. The Graduate Medical Education National Advisory Committee (GMENAC) Report predicted a surplus of 70,000 physicians in 1990 and of 145,000 by the year 2000. This 1980 estimate was modified downward in a Department of Health and Human Services, Bureau of Health Professionals Report completed in May 1983, which predicted a surplus of 35,300 physicians in 1990 and a 51,800 surplus in the year 2000. The discrepancies (50-65 percent) in these two studies, conducted only three years apart, may say more about the reliability of manpower projections than about the supply of physicians. The Health and Human Services Report also projected that the number of active physicians would increase from about 450,000 in 1980 to over 700,000 in the year 2000 if nothing were done to change the productivity rate; and there is general agreement that the largest surpluses are occurring in medical and surgical subspecialties and obstetrics and gynecology. Of course, the number of residents and practitioners is simply a reflection of the number of students entering medical school; so perhaps by seeking to limit residents or specialists, we are looking in the wrong place for solutions. In this respect, it is somewhat reassuring to note that there has been a slight decrease in the number of students enrolled in medical school from the peak of almost 17,000 in 1981 to just under 16,400 in 1984 — a reduction of about three percent.

One obstacle to limiting further the number of medical students is the state capitation supplement, which provides funding for many important programs within the medical school. Nevertheless, it seems inappropriate to consider graduate medical education the "bottleneck" given the number of students released each year into the graduate arena.

On the other side of the equation, the number of foreigntrained physicians admitted to graduate medical education positions in the United States has increased slightly. Roughly 18 percent of the residents currently in training have been educated in foreign schools — of which slightly over half are U. S. foreign medical graduates and slightly under half are alien foreign medical graduates. Most proposals for cost control have suggested that funding for foreign medical graduates be eliminated or reduced.

An interesting occurrence is that this perceived supply-

side surplus has not, as yet, led to a fall in physicians' fees; however, the impact of market forces will undoubtedly become more obvious as the surplus becomes more real. Market forces cannot be expected to work with a physician deficit, and only in the 1980s has an adequate supply been present.

A great deal of discussion and debate has centered on the issue of funding only a limited number of years of graduate medical education. In addition to reducing costs, this approach is seen as having the desirable societal objective of reducing the number of specialists. If funding were, for example, guaranteed for only three years for all U. S. medical graduates, training would be complete for those choosing family practice, general medicine, or general pediatrics, whereas other sources of revenue would have to be found for those house officers in specialties whose Boards required additional training. Many possibilities for such funding have been considered: state support, grants, borrowing by the house officer (deemed reasonable by many, since practice income expectations are generally greater for specialists than for physicians in primary care), other hospital revenues, practice income, or allowing residents to bill and collect fees for service. The impact of this latter alternative on the mentor-student relationship critical to graduate medical education, through introduction of competition for patients, would seem highly undesirable.

By limiting funding to Board eligibility or five years (whichever comes first) of graduate medical education, it has been estimated that approximately \$170 million would be saved by the Medicare program. Restricting the funding to graduates of U. S. medical schools would, if truly operative, save over \$500 million, although it is probably naive to anticipate that Congress will reduce funding for U. S. foreign medical graduates because of their strong political lobby. Thus, the combined effect of these two changes would reduce Medicare costs by 25-30 percent.

Another possibility is to limit funding to primary Board eligibility. Thus, cardiothoracic surgeons, for example, would be funded only through Board eligibility in general surgery. While preserving educational quality, this arrangement would have a relatively small impact on cost reduction and would perhaps have to be accompanied by control of the numbers of specialists produced. The setting of national specialty quotas is beset, however, by many imponderables, such as who would determine them, what data base would be used, and how would reductions be accomplished? Right now, many of the proposals being debated in Congress contain primary board eligibility language. Also being considered, however, is the establishment of a national graduate medical education advisory committee to study health manpower issues. Of concern here is the possibility that resident funding will be tied to perceived manpower needs in the primary care disciplines. A related question is whether all programs in oversupplied disciplines would be cut equally, or whether those of poorer quality would be singled out for reductions. The latter approach will undoubtedly be favored by academically elite programs; just as predictably, those facing elimination or constraint will challenge those judgments in court.

Thought has also been given to making funding dependent upon willingness to serve in undersupplied settings,

either during residency or thereafter, thus favorably influencing the geographic maldistribution of physicians.

The final alternative is to seek additional sources of support. Currently, about 83 percent of resident stipends and benefits are paid from hospital patient revenues, i.e., "sick dollars." The next largest source, state appropriations, supports only about six percent of resident stipends. While it is probably reasonable to ask the users of services to pay for them, the question is whether the educational aspects of graduate medical education should be borne only by the sick, or by all of society, who ultimately benefit from the production of trained physicians. Those who favor preserving the status quo fail to acknowledge that public and private payors are becoming increasingly resistant to funding anything beyong the clinical aspects of patient care. The rise in health maintenance organizations, with their cost-control emphasis, will increase this trend; in fact, it now seems certain that open-ended, retrospective payments of any type will be replaced by prospective methods of cost reimbursement. Whether payors can be forced, shamed, or persuaded for social, ethical, or public image reasons to continue to contribute to financing graduate medical education is problematical. Another possibility is to impose a general revenue tax for the educational costs of residency training; no one is quite sure of, or knows how to determine, the service-to-education ratio in residency training. Further, while a national tax would provide comprehensive financing, its administration by federal officials might make education dependent on the outcome of annual congressional debate and federal budgeteering, much like the National Institutes of Health, which would transfer the control of education from educators to politicians.

Although bureaucratic decisions seldom reflect only logic and reason, it may be hoped that cost control measures emanating from congressional debate will embody the following principles:

1. Of primary concern in any cost-saving mechanism is preservation of educational quality; therefore, funding for all specialties to Board eligibility should be insured.

The control of education should remain in the hands of educators rather than passing to the political arena.

3. Data on which accurate projections of needs for specialty services can be made do not exist; therefore, we should not — except perhaps in a very general way that acknowledges trends — tie funding to specific specialty manpower quotas.

4. Resident costs for patient care services are appropriately borne by those who use them, namely the sick.

5. Resident costs for education are appropriately borne by all of society, since all of society benefits from welltrained physicians.

 Available funds should go first to graduates of U. S. medical schools, although a mechanism should be found to support foreign medical graduates who will return to their own country.

7. Funding for resident positions should be based on national average costs per resident per year.

8. It is highly desirable that cost-saving approaches reflect unity in the medical profession.

Failure to embody the above principles is likely to result in solutions that create more problems than the ones solved.

# The Loop Diuretics: Focus on Furosemide and Ethacrynic Acid

Mary Roesner, Pharm.D.

DIURETIC therapy is widely utilized in medical practice today. However, with the vast number of diuretic agents available, the clinician's decision as to the most appropriate agent to use is not always an easy one to make. One class of diuretic agents, known as the loop diuretics, are most commonly used to manage edema of cardiac, renal or hepatic origin. <sup>1, 2</sup> There are three loop diuretics currently available on the United States market. Ethacrynic acid and furosemide were first introduced in the mid-sixties. Bumetanide, the newest addition to this class, was first introduced into the European market in 1974. This review on loop diuretics will focus primarily on the pharmacologic properties and major clinical applications of furosemide and ethacrynic acid.

#### Pharmacology

Ethacrynic acid is an alpha-beta-unsaturated ketone derivative of phenoxyacetic acid.<sup>2, 3</sup> Both furosemide and bumetanide are sulfonamide compounds but with differing ring attachments. Furosemide contains an anthrone ring attachment and bumetanide is a benzoic acid derivative.<sup>1, 2</sup> Despite the differences in their chemical structures, furosemide, bumetanide and ethacrynic acid can be discussed together because of their similar pharmacologic effects.

The primary site of action for the loop diuretics is along the ascending limb of the loop of Henle. <sup>1, 2, 4, 5</sup> This site of action is located proximal to that of the thiazide and potassium-sparing diuretic agents. Normally 25-30% of the filtered sodium load is reabsorbed throughout the ascending limb. <sup>6</sup> The loop diuretics affect both the medullary and the cortical segments within this portion of the nephron. <sup>7-9</sup> Therefore, impairment of both the concentrating and the diluting powers of the kidney can be seen with these agents. There is also evidence for a proximal tubule effect from these agents but the extent to which this site of action contributes to *in vivo* diuresis remains unknown. <sup>10-13</sup> The loop diuretics may also exert a minor effect on the distal tubule and collecting ducts, but these sites of action are controversial.

Unlike the thiazide diuretics, loop diuretics have a steep dose-response curve which means that as the dose is increased the diuretic response is enhanced. Loop diuretics result in excretion of up to 30% of a filtered sodium load. 14

They also remain effective despite the presence of hypoalbuminemia, acid-base imbalances, and marked reduction in the glomerular filtration rate as low as 10 ml/min.<sup>2</sup> Because the loop diuretics are organic acids and are highly bound to serum proteins, they are not filtered at the nephron to any great extent. 15, 16 They reach their intraluminal site of action by being actively secreted from the blood to the urine via the organic acid transport pathway located in the straight segment of the proximal tubule. Patients with impaired renal function, as seen with chronic renal failure, accumulate organic acid end products of metabolism which compete for transport via this pathway with the loop diuretics. 17, 18 Because of this competition, patients with advanced renal insufficiency may achieve lower peak amounts of diuretic agent at the site of action in addition to a prolonged rate of renal elimination. <sup>17, 19</sup> These patients often require higher doses of the diuretic in order to achieve an adequate amount of the medication at the site of action. Loop diuretics should be used cautiously in these patients and should be discontinued if azotemia or oliguria develops or progresses during therapy.

Since the major action of the loop diuretics is to block sodium chloride reabsorption proximal to the distal tubule, there will be an increased delivery and exchange of sodium for hydrogen and potassium ions at the distal tubule exchange pump, particularly if there is secondary hyperaldosteronism from volume contraction. <sup>14</sup> This could result in the development of hypokalemia, especially in predisposed patients. Calcium and magnesium excretion are usually increased following administration of these agents. <sup>2</sup>, <sup>20</sup>, <sup>21</sup> Like the thiazides, uric acid levels as well as glucose tolerance may be affected by the loop diuretics. <sup>2</sup>, <sup>22</sup>, <sup>23</sup> Intravenous administration of large doses of the loop diuretics has been shown to have a uricosuric effect. However, prolonged oral therapy with these agents has produced hyperuricemia.

#### **Pharmacokinetics**

Ethacrynic acid and furosemide have very similar pharmacokinetic parameters. One major difference between them is their bioavailability profiles (see table 1). Ethacrynic acid given orally is close to 100% bioavailable. Furosemide has been reported to have a bioavailability ranging anywhere from 30 to 85%. <sup>24</sup>, <sup>25</sup> The mean bioavailability for furosemide has been reported to be about 50%. <sup>24</sup> Although the bioavailability of oral furosemide is about one-half that of furosemide given intravenously, no dosage adjustment is required. Most clinical investigations

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References available from the North Carolina Medical Journal editorial office

Table 1 Pharmacokinetic Profile of Ethacrynic Acid and Furosemide\*

	Ethacrynic Acid (PO) (IV)	Furosemide (PO) (IV)
Relative Potency	0.6-0.8	1
Bioavailability (%)	100	65¹
Plasma Protein Binding (%)	95	96-98
Plasma t½ (min)	60	50 <sup>2</sup>
Onset Of Action (min)	within 30	within 60
	within 5	within 5
Peak (min)	120	60-120
	15-30	30
Duration Of Action (hrs)	6-8	6-8
	2	2
Urinary Excretion (%)	30-65	60-70
Metabolized (%)	20-30 <sup>3</sup>	30-40
Biliary Excretion (%)	35-40	6-9

1 Decreased in uremia 2 Prolonged in renal failure, uremia, congestive heart failure, and in neonates

3 Cysteine conjugate

Information derived from Facts and Comparisons, American Hospital Formulary Service, and Kelly MR et al. Clin Pharm Ther

have shown a similar diuretic response from equal oral and intravenous doses of furosemide. 24, 26-28

#### Clinical Applications

Loop diuretics are a useful class of agents in the treatment of various edematous states. However, they are often chosen inappropriately as the first line of drug therapy. Rational selection and adminstration of a diuretic agent for a specific disease entity should be based on the pathophysiology and severity of the disease, as well as the pharmacologic, pharmacokinetic, and adverse reaction profile of the medication.29

Congestive heart failure. Congestive heart failure (CHF) will often respond to bed rest and sodium restriction with or without digitalization. A diuretic agent is indicated if failure of these basic treatment modalities occurs. 30 The goals of diuretic therapy in the treatment of CHF are to 1) increase cardiac performance by decreasing the extent of circulatory overload, 2) decrease the severity of pulmonary edema and 3) remove peripheral edema. 30 Severe pulmonary edema requiring acute therapy is also an indication for diuretic therapy. Generally, the intravenous route rather than the oral route is utilized for the treatment of pulmonary edema.31, 32 The initial beneficial effects seen with the loop diuretics in the treatment of pulmonary edema associated with CHF are thought to be due more to an increase in venous capacitance resulting in decreased preload than to their diuretic action.<sup>33</sup> Loop diuretics are not generally indicated as first-line agents in the treatment of CHF.30 Overdiuresis can precipitate acute decreases in blood pressure in the failing heart as a result of acute decreases in preload. Therapy with a loop diuretic is indicated if there is a marked decrease in the glomerular filtration rate (<20 ml/min), if resistance to the thiazide diuretics has occurred

or if severe pulmonary edema is present.<sup>34</sup>

Edema Associated with Hepatic Disease. Indications for initiation of diuretic therapy in the management of edema associated with hepatic disease includes 1) inadequate response to salt and water restriction, 2) impaired cardiovascular or respiratory function and 3) tense ascites. 35-37 The goal of diuretic therapy is to provide a gradual but sustained diuresis.35 Gradual diuresis allows equilibration of ascitic fluid and extracellular fluid. If diuresis occurs too rapidly, depletion of extracellular fluid will occur, but ascitic fluid will remain. Another caution of overdiuresis is that intravascular volume contraction can precipitate hepatic encephalopathy. In general, patients with ascites only can safely mobilize up to 300 ml/day of ascites fluid, and patients with both ascites and edema can mobilize up to 800 ml/day of nonascitic fluid and no more than 300 ml/day of ascitic fluid.35 Most cirrhotic patients have high circulating levels of aldosterone which leads to decreased sodium excretion, increased potassium excretion, and further edema formation. 37, 38 For this reason, spironolactone, an aldosterone antagonist, is normally considered the diuretic of choice. 39 A thiazide diuretic could be added to spironolactone if the urinary sodium to potassium ratio is not reversed or if upon reversal of the ratio, insufficient diuresis occurs. 40 Loop diuretics should be used in place of the thiazide diuretics only when the glomerular filtration rate falls below 20 ml/min or if thiazide diuretics are ineffective following an adequate trial period. Loop diuretics are not first-line agents because they are very potent and generally have a shorter duration of action than the thiazide diuretics.37, 41

Acute Renal Failure. Diuretic therapy has been employed in the early stages of acute renal failure to induce a diuresis in the oliguric patient who has had pre-renal factors corrected. 42. 43 The proposed rationale behind diuretic therapy in acute renal failure is to enhance urine flow and possibly convert an oliguric state to a non-oliguric state. 42 The mortality rate has been shown to be much lower for the non-oliguric state (26%) than for the oliguric state (50%). 43, 44 Either mannitol or the loop diuretics may be used to induce diuresis. 43, 45, 46 Mannitol does not enter the cells and is not reabsorbed by the renal tubules. It causes plasma volume expansion with a resultant increase in glomerular filtration rate. 46 Mannitol has also been shown to prevent cell swelling which may be its most important protective role. 47 Loop diuretics, such as furosemide, have also been helpful in ameliorating acute renal failure.43 Since they are not filtered to any significant extent at the glomerulus, they may prove useful in situations where mannitol has failed or is contraindicated. 42, 48 Contraindications for mannitol include CHF, excessive hydration, and chronic renal failure.

Miscellaneous Uses. Loop diuretics may be used in the management of hypertension. 41, 49 They are not considered first-line agents in the treatment of hypertension and should be reserved for the more resistant cases. 41, 50 Loop diuretics have also been used in the management of hypercalcemia. 51, 52 A large percentage of the sodium and calcium load is reabsorbed in the loop area. By inhibiting active chloride transport at this site, loop diuretics cause an increased excretion of both sodium and calcium. 51-53 It is

important to replace sodium and water losses during diuretic therapy in order to maintain a calcium excretion.<sup>53</sup> Volume depletion results in a shrinkage of extracellular fluid volume which in turn leads to an enhanced proximal tubule reabsorption of sodium, water, and calcium.

#### Combination Therapy with a Loop and Thiazide Diuretic

True resistance to a loop diuretic agent is relatively rare. <sup>54</sup> When refractory edema does occur, combination therapy with a thiazide diuretic and a loop diuretic may be beneficial. A synergistic effect with this combination regimen has been documented. <sup>55-57</sup> The postulated mechanism behind this combination therapy is that the thiazide diuretic inhibits the distal tubular sodium reabsorption that normally occurs when a loop diuretic is administered as the sole agent. However, this regimen is not without problems. <sup>58</sup> As pointed out in a recent editorial by Oster et al, at least three deaths and 35 FDA reported fluid-electrolyte-azotemia type adverse reactions have occurred with this combination regimen. <sup>54</sup>

#### **Adverse Reactions**

The major side effects associated with administration of the loop diuretics include volume depletion, hypotension, hypokalemia, hyperuricemia, hypocalcemia and glucose intolerance.1, 2 The most frequently reported adverse effects include headache, nausea, vomiting, diarrhea, dizziness and muscle cramps. 1. 2 Ototoxicity has also been reported with the loop diuretics. There seems to be a higher incidence of ototoxicity when loop diuretics are administered 1) to patients with impaired renal function, 2) intravenously at faster than normal rates, 3) in higher doses and 4) in association with other ototoxic medications. 59-61 The results of a study in which patients had creatinine clearances less than 20 ml/min stated that intravenous administration of furosemide at a rate of 25 mg/min produced a noticeable, transient hearing loss in 60% of the study group. 59 They also noted that infusion of furosemide at 15 mg/min produced hearing losses but that the patients were not aware of any hearing impairments. They concluded that administration of furosemide at a rate of less than 4 mg/min would avoid losses of hearing acuity. Ethacrynic acid has never been utilized to the extent that furosemide has. The reason for this remains unclear. It may be due in part to the higher incidence of gastrointestinal bleeding associated with ethacrynic acid or due to early studies of ethacrynic acid administration which revealed both transient and permanent deafness. 30, 62 Other factors to be considered are that furosemide does not require reconstitution before it can be administered intravenously, and that ethacrynic acid may potentiate the anticoagulant effects produced by warfarin. 63, 65

#### Dosage and Administration

Ethacrynic acid is available as oral 25 mg and 50 mg tablets and as an intravenous product containing 50 mg per vial. The usual oral dose in the management of edematous states is 50-200 mg a day in divided doses.<sup>2, 65</sup> It is best to take ethacrynic acid on a full stomach to decrease the risk of

gastrointestional toxicities. <sup>2, 66</sup> The dose is usually adjusted by increments of 25-50 mg depending on the patient's response. <sup>65</sup> The intravenous dose of ethacrynic acid is 50 mg or 0.5-1.0 mg/kg administered over several minutes. <sup>65</sup> Ethacrynic acid should not be given intramuscularly or subcutaneously because of the localized pain and irritation produced by this product. <sup>65</sup> It should not be mixed with whole blood products or their derivatives. Ethacrynic acid is compatible with dextrose 5% and normal saline solutions. <sup>65</sup>

Furosemide is available as oral 20 mg, 40 mg and 80 mg tablets, an oral solution of 10 mg/ml, and injections of 20 mg, 40 mg and 100 mg. The usual oral dose of furosemide in the management of edematous states is 20-80 mg a day as a single dose. 67 A second dose may be given 6-8 hours later if an adequate response has not been achieved. Oral doses may be titrated up to 600 mg/day in the treatment of severe edema. 67 The dose normally utilized in the management of edema is 20-40 mg administered intravenously or intramuscularly over a 1-2 minute period.<sup>67</sup> Doses may be increased in increments of 20 mg every two hours until the desired response is achieved. When treating pulmonary edema, the recommended dose is 40 mg intravenously over 1-2 minutes. 67 If the response is unsatisfactory after one hour, a second dose of 80 mg may be given. Furosemide is also commonly used to increase calcium excretion. The dose commonly utilized in the treatment of severe hypercalcemia is 80-100 mg intravenously or intramuscularly. 67 This dose may be repeated every 1-2 hours until a desired response is achieved. In the management of hypertension, the normal dose is 40 mg orally twice daily. <sup>41, 67</sup> However this should be individualized according to the patient's response. Furosemide is compatible with dextrose 5%, lactated ringer's or normal saline solutions.

#### **Drug Interactions**

Both ethacrynic acid and furosemide may decrease the renal clearance of lithium.<sup>68, 69</sup> If concomitant therapy is required, the patient should be monitored carefully and lithium dosages should be adjusted appropriately. Since both ethacrynic acid and furosemide are also capable of inducing a hypokalemic state, any patient receiving a digitalis glycoside may be predisposed to digitalis toxicity.70 Electrolyte levels should be monitored periodically. Ethacrynic acid has been shown to displace warfarin from albumin binding sites. 63. 64 Potentiation of its anticoagulant effect may occur, requiring a reduction in the warfarin dose. A study done by Nilsson et al has shown that furosemide can be safely administered during warfarin therapy without risk of an interaction occurring.<sup>71</sup> Phenytoin has been demonstrated to inhibit the gastrointestinal absorption of furosemide by as much as 50%. 72 Indomethacin may decrease the natriuretic and hypotensive effects of furosemide. 73 Indomethacin has also been shown to block furosemide-induced increases in plasma renin activity. Furosemide has been reported to prolong the neuromuscular blockade in patients receiving nondepolarizing neuro-muscular blocking agents. <sup>74, 75</sup> In general, administration of other ototoxic agents with either ethacrynic acid or furosemide may result in an increased incidence of ototoxicity.60, 76

#### Potassium Supplementation

Is potassium supplementation necessary when initiating diuretic therapy? The answer to this question is not readily apparent and considerable controversy surrounds the issue. 77-79 Serum potassium levels frequently decline during long-term diuretic therapy, although this is rarely progressive or pronounced.<sup>77, 80</sup> Patients who are ambulant with mild hypertension can usually tolerate a mild hypokalemia. 77, 78 Recommendations for this patient population would include monitoring serum potassium levels before therapy and then at 1-2 month intervals thereafter until a pattern emerges. Supplementation would not be necessary unless the serum potassium level falls below 3 mEq/l or if the patient becomes symptomatic. In other patients, even a slight decline in serum potassium levels may be dangerous.<sup>77, 78</sup> In patients receiving digitalis medications, a moderate fall in the potassium level could precipitate a fatal arrhythmia. In the cirrhotic patient, low potassium levels may precipitate a hepatic coma. In diabetic patients, there is a risk of increased glucose intolerance. Initiation of potassium supplements during diuretic therapy in these patient populations would seem to be a reasonable decision.

Fatal hyperkalemia as a result of potassium supplementation is another concern. Adequate documentation of serious hyperkalemia in the ambulatory patient population is not available. <sup>78</sup> However, a study done by Lawson showed that a hospitalized patient receiving a potassium supplement had a 1 in 200 chance of developing a fatal or life-threatening hyperkalemia. <sup>81</sup> The frequency was high-

est for elderly patients, for patients with impaired renal function, for patients receiving both oral and intravenous supplements and for patients receiving potassium chloride along with diuretic agents. In this study, 86% of the patients were given the potassium supplement to prevent rather than to treat hypokalemia. Other patient populations that should be observed closely are those receiving additional potassium-wasting medications or those experiencing any episode that could cause a further decline in serum potassium levels. The latter population would include patients with diarrhea, vomiting, anorexia, or excessive sweating. <sup>77</sup> Other methods that could be utilized in reducing the risk of developing hypokalemia include 1) intermittent diuretic therapy, 2) increased dietary intake of potassium sources and 3) potassium-sparing diuretic therapy. <sup>77</sup>

#### Conclusions

Both ethacrynic acid and furosemide are loop diuretics indicated for the management of edema associated with renal disease, hepatic disease, and congestive heart failure. They are potent diuretics and should generally be reserved for use in resistant cases of edema, in treatment of severe pulmonary edema, in patients with renal impairment and in patients resistant to first-line agents. The loop diuretics have also been used in the management of hypercalcemia and hypertension. In general, furosemide and ethacrynic acid have similar pharmacokinetic and adverse reaction profiles. Furosemide is more widely used than ethacrynic acid. The reason remains unclear but may be related to convenience and familiarity with furosemide as well as the interaction between ethacrynic acid and warfarin.

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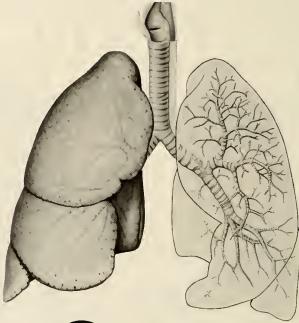
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reactions may occur in patients with on without a history of allergy or bronchal asthma. Possible exacerbation or activation of systemic lugus erythematous has been reported with thiazide diuretics.

Precautions: The bioavailability of the hydrochtoriazide component of 'Dyazide' is about 50% of the bioavailability of the single entity. Theoretically, a patient transferred from the single entitles of Dyrenium firiamterenc, SK&F CO J and hydrochtoriazide may show an increase in blood pressure or fluid retention. Similarly, it is also possible that the lesser hydrochtoribazide bioavailability outlead to moreased serum patiessum levels. However, extensive clinical experience with 'Dyazide' suggests that these conditions have not been commonly observed in clinical practice. On periodic serum electrolyte determinations fapricularly imponant in patients vomiting excessively or receiving parenteral fluids, and during concurrent use with amphoterion B or corticosteroids or corticotropin (ACTHI). Penodic BUN and serum creatinine determinations should be made, especially in the elderly, disbettics or those with suspected or continend creal finical finishing the serum creatinine determinations should be made, especially in the elderly, disbettics or those with suspected or continend creal finishing the serum creatinine determinations. Blood dyscrasias have been reported in patients were requirily for possible blood dyscrasias, liver damage, other idiosyncratic reactions. Blood dyscrasias have been reported in patients receiving transference, and leukopenia, thrombocytopenia, agranulocytosis, and aglastic and hemolytic anemia have been reported with thiazides. Thiazides may cause manifestation of latent diabetes melitus. The effects of orol artificoagulants may be decreased when used concurrently with hydrochlorothizaide, dosage adjustments may be necessary. Clinically insignificant reductions in arterial responsiveness to norepinephrine have been reported. Thiazides have also been shown to increase the paralyzing effect of

Thiazides may add to or potentiate the action of other antihypertensive

Diuretics reduce renal clearance of lithium and increase the risk of lithium

Adverse Reactions: Muscle cramps, weakness, dizziness; headache, dy mouth, anaphylatis, rash, urticaria, photosensitivity, purpura, other dermatological conditions; nausea and vemiting, diarnea, constigation, other gastrointestinal disturbances; postural hypotension imay be aggravated by alcohol, babiliturates, or narcotics). Necrotizing vasculitis, pareethesias, icterus, pancrealitis, arribopsia and respiratory distress including pneumonitis and pulmonary edema, transient blurred vision, sialadenitis, and veritigo have occurred with thiazides alone. Triamterene has been found in renal stones in association with other usual calculus components. Rare incidents of acute interstitula nephritis have been reported in notence has been reported in a few patients on 'Dyazide', although a causal relationship has not been established. has not been established

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#### Letters to the Editor

#### Musings on Medicare, HCFA, and the Medical Review of North Carolina

#### To the Editor:

I couldn't attend the "training" session held by the MRNC on Wednesday, December 4 in Raleigh, although an invitation was extended. I understand that the dinner was acceptable (and "free") and that attendance qualified those physicians present to be physician reviewers for the Medical Review of North Carolina. Of course they will be recompensed for this work and will join an extensive system which has been created to cut Medicare cost, basically by denying charges for hospitalization. This system reviews the charts of hospitalized patients and "denies" based on guidelines for appropriate admission sent down by the Health Care Financing Administration (HCFA) of the Department of Health and Human Services of the Executive branch of the Federal Government.

As a practicing internist in the trenches (though at a university hospital on a full-time salary), I have experienced with interest the interpretation and implementation of the HCFA guidelines. This has involved me in the past several months in extensive correspondence with the Medical Review of North Carolina staff as the process of denial, appeal, re-denial and re-appeal\* has and is taking place. The communications with "the system" involve extensive computer generated letters (with stamped signatures) and fascinating individualized "reasons for denial" coming from the anonymous M.D. reviewers. The denials usually hinge on the lack of technical/invasive procedures (such as parenteral drugs) or the fact that the procedures that were performed "could have been performed as an outpatient." Of course almost any procedure can take place as an outpatient. Good medicine, however, requires a sense of appropriateness and "care" which dictates that hospitalization (with its dangers) is more appropriate in certain instances. In my dismay and anger over the "Monday morning quarterbacking" of my clinical judgment, I have appealed every denial case and so far am batting 1 out of 4.

I am sure that my peers who are "reviewing" are carefully reading the completely reproduced chart (think of the cost, paper and busy work required by my hospital to provide this). They are then following the HCFA guidelines — as did the nurse-technicians who first "flagged" the case.

Reading between the lines, I can imagine HCFA directives setting goals (?quotas) for rates of rejection, charges, guidelines, and demanding different criteria, as the HCFA's expressed goal is to cut down Medicare disbursements to the hospitals, which then have to recoup the disallowed Medicare charges from other sources. I am curious as to the real savings to the public, particularly in light of the

huge direct costs of running these review organizations, and the equally large costs absorbed by the hospitals (and indirectly passed on to the paying patients) who must comply with the review guidelines to receive any reimbursement from Medicare. My hospital (North Carollina Memorial Hospital) estimates a cost of at least \$100,000 in the first nine months of 1985, with almost \$900,000 in Medicare payment being denied. The indirect costs in physician time as physicians serve on utilization committees and as they "appeal" cases (if they have the energy and motivation) is not factored.

As I have appealed my cases, I have been sharing the correspondence about the cases with the media (with patients' permission). This is being done so that the public can understand the following:

a) How the current federal administration is manipulating the promise of Medicare for the elderly and passing on costs to the non-Medicare population, while at the same time not really effecting *any* savings.

b) How it is creating, intrusively, a style of care which changes the physician's role from servant/advocate of the patient to servant/advocate of the system and is moving Medicare from an ''insurance'' idea to a welfare idea.

The major argument for supporting/encouraging the Medical Review of North Carolina is that this organization (which is us) would be replaced — if we did not have it — by an imposed organization (which is them). Thus far MRNC has been a servant of HCFA and its regulations and guidelines. If by implementing these guidelines, it coopts the profession into roles and behaviors that destroy the traditional primary purpose of proper care for our patients, I feel that we should disband MRNC, let "them" fight us publicly as they create "emperor's clothes," and let the public have physicians who are in the business of caring for the patient, not the system.

James A. Bryan, II, M.D. Department of Medicine University of North Carolina Chapel Hill 27514

#### Reye Syndrome

#### To the Editor:

I read with interest Dr. Denny's timely and thoughtful review of the Reye syndrome-aspirin controversy. This syndrome bears the name of Dr. Reye, an Australian physician who was lead author of the 1963 Lancet paper commonly recognized as the first report of this 'new' disease in children. However, the very same month the Lancet article was published, a report describing a fatal encephalitis-like illness in 16 North Carolina children was published in the North Carolina Medical Journal. In reading this paper, there can be little doubt that these children died from what is now referred to as Reye syndrome. Both reports are beautiful examples of the importance of careful

<sup>\*</sup> There is really no mechanism for this.

observational research in identifying new diseases and monitoring the decline of old ones.

Hugh Craft, M.D., M.P.H. Roanoke Memorial Hospitals Roanoke, VA 24033 2 Johnson GM, Scurletis TD, Carroll, NB: A Study of Sixteen Fatal Cases of Encephalitis-like Disease in North Carolina Children N.C. Med J 1963;24:464-73.

#### Editor's Note:

The interested reader may want to review the article by Riela and Roach on Reye's Syndrome: Twenty Years in Perspective published in the June 1983 issue of the *North Carolina Medical Journal* (44:351-5).

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Reye RDK, Morgan G, Baral J: Encephalopathy and fatty degeneration of the viscera: a disease entity in childhood. Lancet 1963;2:749-52.

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#### IN STATE

#### February 12

Affective Disorders: Diagnosis and Treatment

Place: Greenville

3.5 hours Category 1 AMA Credit:

Fee: \$30

Info: Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/ 758-5200, ext. 208

#### February 13-14

Laser Workshop in Neurosurgery

Place: Chapel Hill

15 hours Category I AMA Credit:

\$750

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill Info: 27514. 919/962-2118

#### February 14-15

House Officer Selection

Place: Chapel Hill

Credit: 12 hours Category 1 AMA

\$335 Fee:

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514, 919/962-2118 Info:

#### February 14-16

Family Physicians Weekend

Place: Raleigh

Credit: 8 hours prescribed

Mary Anna Hendley, NC Academy of Family Physicians, Box Info: 20146, Raleigh 27619. 919/781-6467

#### February 16-19

Improving Residency Rotations

Rougemont

20 hours Category I AMA

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### February 17-19

Selected Topics for the Practicing Clinician

Place: Durham

Credit: 24 hours Category I AMA

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### February 21

Pediatrics Day 1986

Place: Greenville

Credit: 6 hours Category I AMA Fee:

Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/ 758-5200, ext. 208

#### March 4

Duke Tuesday

Place: Durham

Credit:

5 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710, 919/684-6878 Info:

#### March 5

Early Diagnosis and Management of Cancers of the Aero Digestive and

Genitourinary Tract Place: Chapel Hill

Robert McKinstery, DMD, 919/966-2754

#### March 6-7

Damaged DNA: Its Structure and Recognition

Place:

Pam Upchurch, Lineberger Cancer Research Center, UNC, Chapel Hill 27514 919/966-3036

#### March 6-8

7th Diving Accident and Hyperbaric Oxygen Treatment

Durham Place:

Credit: 21 hours Category I AMA

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

March 6-13

Review of Clinical Chemistry for Practicing Pathologists and Clinical

Chemists

Place: Greenville

40 hours Category 1 AMA Credit:

Fee: \$315 Info

Office of CME, ECU, Box 7224, Greenville 27835-7224. 919/

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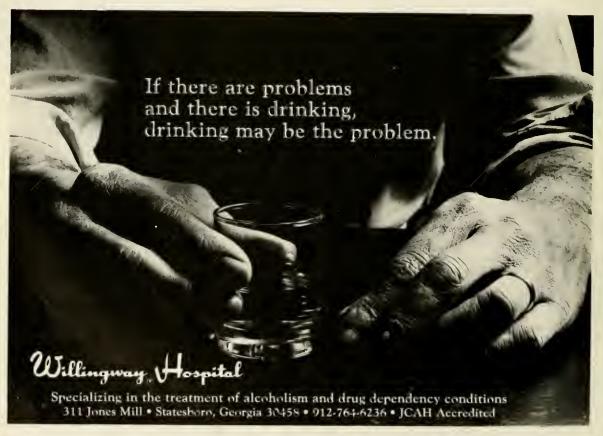
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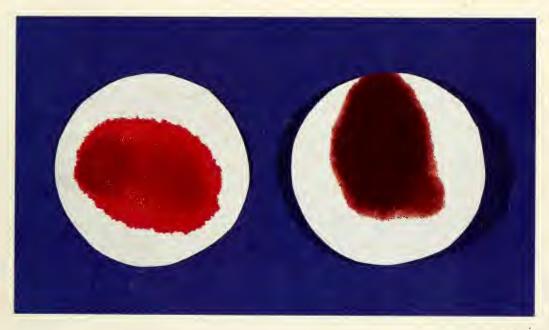
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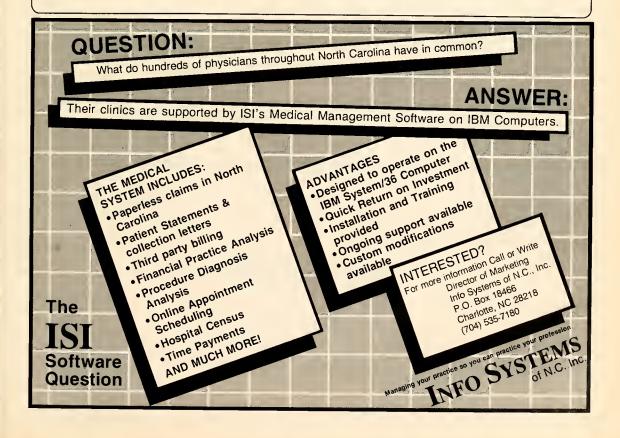
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# Brown Blood: Understanding Methemoglobinemia

Paul R. Conkling, M.D.

HEMOGLOBIN is a dye. When oxygenated, it is red; when deoxygenated, it is blue. A drop in oxygen saturation in the arterial blood is the most common cause of a change in the expected color of arterial blood. We call this change in color cyanosis. The presence of another dye in the blood, methemoglobin, may be missed in a patient in whom we depend too greatly on the oxygen saturation to explain cyanosis. We recently observed an acutely ill patient who became hypoxic and cyanotic in the hospital. The stage was set for making an error in recognizing and treating methemoglobinemia.

#### Case Report

A 34-year-old black man from rural North Carolina developed severe congestive heart failure due to ethanol use or a viral infection. He was referred to this medical center, where laboratory studies were normal except for a deficiency of glucose-6-phosphate dehydrogenase (G6PD) by a screening test. The patient entered a congestive heart failure treatment study in which he received prazosin, apresoline, isosorbide or placebo. He did well for two years, when his symptoms began to increase. He was admitted due to severe shortness of breath.

On admission, the patient was lethargic. His heart rate was 110/min; blood pressure, 110/90; respiratory rate, 36/min; and temperature, 98.4° F. There were diffuse rales throughout both lungs, jugular venous distention to the angle of the jaw while sitting, cardiomegaly, and prominent third and fourth heart sounds. There was marked peripheral edema. His hemoglobin was 14.5 g/dl and the white blood cell count was 6,700/mm³. While breathing room air, his arterial blood pH was 7.52; PO<sub>2</sub>, 74; PCO<sub>2</sub>, 21; O<sub>2</sub> saturation, 96%. Other laboratory studies were normal.

On the second hospital day, his arterial PO<sub>2</sub> fell below 50 and he was transferred to the coronary care unit. A balloon-tipped pulmonary artery catheter gave readings consistent with severe congestive heart failure. He appeared to improve after treatment with intravenous nitroprusside and dopamine.

On the third hospital day, he vomited a small amount of blood. His hemoglobin was 13.5 g/dl and his white blood cell count had risen to 21,700/mm.<sup>3</sup> Blood, urine, and sputum cultures revealed no growth. He was treated with antacids for his hematemesis. Over the next 24 hours, he

developed marked cyanosis; dopamine was changed to dobutamine, and nitroprusside was continued.

At the start of the fourth hospital day, the patient appeared profoundly ill. Oxygen was started and another arterial blood gas was ordered. This revealed pH, 7.55;  $PO_2$ , 92;  $PCO_2$ , 24;  $O_2$  saturation, 98%. While drawing the blood gas, the physician on duty noted a peculiar chocolate color of the blood. Recalling the patient's cyanosis, he repeated the blood gas, this time measuring the  $O_2$  saturation on a spectrophotometer rather than calculating it from the pH and  $PO_2$ . Now the  $O_2$  saturation was 72%. Further tests showed the arterial blood sample contained 24.5% methemoglobin (normal < 1%).

Because of the elevated methemoglobin level, the patient was given intravenous methylene blue, 1 mg/kg. Multiple vasoactive medicines were tried, without benefit. Unfortunately, the patient became anuric and hyperkalemic, requiring hemodialysis. At the beginning of the fifth hospital day, the patient became asystolic and died.

#### Discussion

Normal hemoglobin consists of four protein chains, each with a heme moiety containing iron in the ferrous (Fe<sup>2+</sup>) state. Ferrous iron can bind an oxygen molecule and is essential for oxygen transport to peripheral tissues. In methemoglobin, the iron is oxidized to the ferric (Fe<sup>3+</sup>) state. The ferric iron of methemoglobin cannot bind oxygen. Furthermore, methemoglobin shifts the oxygen dissociation curve of normal hemoglobin to the left, decreasing even more the availability of oxygen to peripheral tissues.

Normal hemoglobin can be converted to methemoglobin by a reversible reaction (hemoglobin-Fe<sup>2-</sup> ≠hemoglobin-Fe<sup>3+</sup>). In the normal red blood cell, the equilibrium between normal hemoglobin and methemoglobin is such that >99% of all hemoglobin is in the ferrous (normal hemoglobin) state and <1% is in the ferric (methemoglobin) state.<sup>2</sup> An increased circulating level of methemoglobin is called methemoglobinemia.

Methemoglobin has a dark, red-brown color which is responsible for the dusky blue cyanosis seen in patients with methemoglobinemia. Methemoglobinemia has been recognized clinically for over fifty years by this characteristic color. In a simple bedside test, normal venous blood placed on white filter paper becomes bright red within seconds due to exposure of the hemoglobin to oxygen in the atmosphere. With methemoglobinemia, venous blood placed on the filter paper appears red-brown and does not

From the Department of Medicine, Duke University Medical Center, Durham 27710.

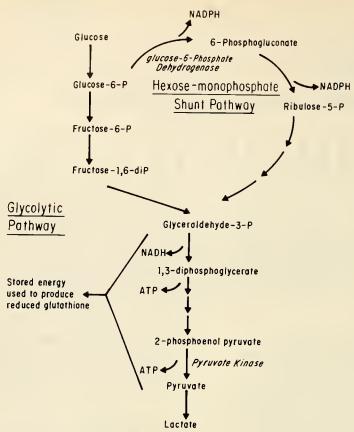


Figure 1. Metabolic pathways important in the erythrocyte.

change color (see cover photo).

Normal hemoglobin is converted to methemoglobin by several mechanisms. Most important for our consideration is that of exposure to strong oxidizing compounds. <sup>3</sup> Table 1 is a partial list of compounds that have been reported to produce methemoglobinemia. This list includes many common chemicals such as aniline dyes, some insecticides, chlorates and naphthylamines. Recently, butyl nitrite,

A Partial List of Drugs and Chemicals that May Induce Methemoglobinemia Acetanilid Nitrofurantoin Acetophenetidin Nitroglycerin Amyl nitrite Nitroprusside Antimalarial agents -Phenacetin Phenetidin primaquine, chloroquine Benzocaine Phenois Butyl nitrite Phenytoin (Dilantin) Chlorates Pyridium Dapsone Quinones Lidocaine Resorcinol Moth balls Sodium nitrite Naphthylamines Sulfonamides **Nitrates** Trinitrotoluene Nitrogen oxide

sniffed recreationally, has been reported to induce clinically significant methemoglobinemia. Even more important are a number of medications used in clinical practice, such as amyl nitrite, nitroglycerin, nitroprusside, phenacetin and phenytoin (Dilantin). Fortunately, despite their wide use, very few persons exposed to these compounds develop methemoglobinemia. Why is this true?

The normal red blood cell avoids methemoglobinemia through two mechanisms: by reducing methemoglobin back to hemoglobin, or by reducing oxidant compounds before they can produce methemoglobinemia. Two enzymes accomplish the first mechanism. NADH-dependent methemoglobin reductase accounts for about 95% of the reducing activity of the normal red blood cells. Deficiency of this enzyme results in congenital methemoglobinemia. Another enzyme, NADPH-dependent methemoglobin reductase, provides the remaining 5% of the reducing activity of the red blood cell. Deficiency of this enzyme is usually not clinically significant. This enzyme depends on the activity of the hexose-monophosphate shunt pathway, the only source of NADPH in the red blood cell (see figure 1). Patients such as ours, who have G6PD deficiency, may lack NADPH. When the need to reduce methemoglobin is extreme, they may not be able to respond.

The red blood cell also prevents methemoglobinemia by

using reduced glutathione to reduce strong oxidizing compounds before they can produce methemoglobin. The red blood cell generates reduced glutathione via the glycolytic pathway. Note that impairment of the glycolytic or the hexose-monophosphate shunt pathway (as in pyruvate kinase deficiency or G6PD deficiency) makes the red blood cell susceptible to toxic oxidant injury (see figure 1).

Despite two protective mechanisms, acquired methemoglobinemia does occasionally occur following exposure to one of the compounds listed in table 1. Even so, not all cases of methemoglobinemia require specific therapy. The characteristic dusky-blue cyanosis of methemoglobinemia can be recognized when the methemoglobin concentration reaches 1.5 g/dl (methemoglobin concentration of about 10%). Mild symptoms, such as fatigue due to decreased oxygen delivery, usually do not occur until the methemoglobin concentration reaches 20-40%. Levels of methemoglobin greater than 60% may be lethal. Thus, low levels of methemoglobin may produce remarkable physical findings with minimal clinical effect. In these cases, supportive and symptomatic care is usually adequate. If there is an inciting agent, this should be removed.

Higher levels of methemoglobinemia require specific treatment. Methylene blue is the most useful agent in the acute setting. It acts as a cofactor with NADPH-dependent methemoglobin reductase to convert methemoglobin back to hemoglobin (see figure 2). Methylene blue therapy can be remarkably effective, with cyanosis disappearing within one hour. It is given intravenously in a dose of 1.0 mg/kg body weight over five minutes. Side effects are few.

However, methylene blue does not always reverse methemoglobinemia. As noted before, the NADPH-dependent methemoglobin reductase enzyme depends on the availability of NADPH, generated solely by the hexose-monophosphate shunt pathway in the red blood cell. When the NADPH supply is limited, as in G6PD deficiency (figure 1), methylene blue cannot convert methemoglobin to hemoglobin. Such may have been the case with our patient. He was admitted to the hospital with profound congestive heart failure and hypoxia, and subsequently received many agents, including nitroprusside and nitroglycerin, which appear to have induced moderate levels of



Figure 2. Role of methylene blue in the reduction of methemoglobin to hemoglobin.

methemoglobinemia and hemolysis. Methylene blue failed to correct his methemoglobinemia, perhaps because of his underlying G6PD deficiency.

Other therapies have been used to treat toxic methemoglobinemia. Oral ascorbic acid has been tried but is not useful acutely due to the slow onset of action. Hyperbaric oxygen, which would not convert methemoglobin to hemoglobin, could have been tried in this patient in order to increase the oxygen dissolved in his plasma. Exchange transfusion also could have been attempted in order to remove the patient's methemoglobin-containing erythrocytes. However, the large fluid shifts produced by this procedure might have hastened his death due to his severe congestive heart failure.

In summary, it is important to recognize methemoglobinemia as one cause of cyanosis. An understanding of the biochemistry and physiology of methemoglobin formation and reduction permits proper treatment. Drug-induced methemoglobinemia is the most frequent form encountered by the practicing physician. Appropriate therapy should be determined by the clinical setting and any complicating disorders, such as G6PD deficiency.

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### Hemoglobin SC Disease Causing Ischemic Necrosis

Peter Larson, M.D., Mark Mayer, M.D., Lee R. Berkowitz, M.D., and Eugene P. Orringer, M.D.

 Thorough examination and hematologic evaluation of a patient with ischemic lesions of her fingertips disclosed hemoglobin SC disease, which could have been exacerbated by a planned contrast arteriogram.

THIS is the story of a 35-year-old black woman who had had painful and cool cyanosis of the tips of the first three fingers of the left hand for two weeks. She was a nonsmoker and denied prior history of embolic events, Raynaud's phenomenon, or similar ischemic symptoms of the hand. Two of her six children had sickle cell trait. Subsequent to thrombosis of the deep veins of the left leg at the age of 15, she noted occasional episodes of skin ulceration over the left medial malleolus.

The second finger on the left hand was cool and cyanotic from its tip to the distal interphalangeal joint. The tips of the first and third fingers of the left hand were also cool but without cyanosis. Decreased capillary filling was apparent after ulnar artery compression. There were dark, ischemic, ulcerated lesions at the tips of the second and third fingers. The larger lesion, present on the second finger, measured approximately 0.5 cm in diameter. There was also a well-healed, circular ulcer over the left medial malleolus. Peripheral pulses were symmetrical and intact. No lymph nodes were palpable. There was a grade 2/6 systolic ejection murmur at the left sternal border. The liver and spleen were not palpably enlarged. Proliferative retinopathy was not found.

Laboratory studies included a hemoglobin of 10.9 g/dl and a hematocrit of 32%. The white blood count and platelets were normal. The peripheral blood smear revealed target cells and an occasional sickled form. A chest film was normal but "codfish" deformity of the vertebral bodies was noted. An echocardiogram, looking for a cardiac source of emboli, was normal. Because of the history of sickle cell trait in two children, the findings on the peripheral blood smear and the "codfish" deformity of the vertebral bodies, a hemoglobin electrophoresis was carried out, which confirmed the diagnosis of hemoglobin SC disease.

The patient was treated with oxygen and IV fluids. She had prompt resolution of her pain and cyanosis, and within a few days the ulcers began to heal. She was discharged

from the hospital one week later. Since this episode, she has experienced one recurrence of the ulcer on her left lower extremity and two minor vasocclusive crises, each of which has been managed on an outpatient basis.

#### Discussion

Hemoglobin SC disease, which was originally described in 1951, is now recognized as the second most common sickle hemoglobinopathy.2 A recent, prospective series by Ballas et al indicates that these patients experience many of the same complications observed in patients with homozygous sickle cell anemia, though in most instances the frequency of the various complications is less in the hemoglobin SC group.3 Striking exceptions to this general observation are the higher frequencies of proliferative retinopathy, renal papillary necrosis, and major vessel thromboembolic events in the hemoglobin SC group.3 Other investigators have reported that hemoglobin SC patients also have a higher incidence of occlusive pulmonary vascular disease and pulmonary hypertension. 4-6 None of these reports, however, describes a patient with peripheral arterial ischemia as is reported here.

Why patients with hemoglobin SC disease should have such high incidences of these various complications remains uncertain. Ballas and a number of other investigators have suggested that the higher hemoglobin levels found in the SC patients (relative to hemoglobin SS patients) and the resulting increase in whole blood viscosity could be clinically significant. A second, perhaps even more relevant question is why patients with hemoglobin SC disease should have any abnormalities at all, since individuals with the AS genotype (sickle trait) are essentially asymptomatic. In an attempt to answer this question, Bunn and his co-workers have examined the molecular and cellular pathogenesis of hemoglobin SC disease.7 These authors hypothesized that at least three factors could be responsible for the increased hemoglobin polymerization in SC cells (relative to hemoglobin AS cells). These factors include (a) an increased tendency of hemoglobin C to interact and copolymerize with hemoglobin S; (b) a higher percent of hemoglobin S found in the blood of SC heterozygotes than

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is typically present in AS heterozygotes; and (c) an increased intracellular hemoglobin concentration (MCHC) in SC red cells when compared with AS red cells. The results of their study showed, rather surprisingly, that there was no difference in the tendency of hemoglobins A and C to co-polymerize with hemoglobin S. These authors did find, however, that SC heterozygotes possess a higher percentage of hemoglobin S (50%) than do sickle trait individuals (40%). In addition, the MCHC of SC heterozygotes is substantially higher (34.3%) than is found in AS heterozygotes (31.9%). These authors then concluded that the abnormalities found in patients with hemoglobin SC disease seem to be caused by the high percentage of hemoglobin S in the blood and the high MCHC in the cells.

It was fortunate that the diagnosis in our patient was established because otherwise an arteriogram would have been performed. The hypertonicity of the IV contrast material, by raising the MCHC still further, would have increased the tendency of these cells to sickle. The resulting impairment of whole blood flow would have reduced the already compromised blood supply to the left hand. The diagnostic evaluation of patients presenting with ischemia

of small blood vessels should include an adequate past and family history as well as a review of red cell morphology. If abnormalities are found, ischemia due to a sickle hemoglobinopathy should be considered. Appropriate therapy, including oxygen and vigorous hydration, should be instituted, and vascular radiologic studies employing hypertonic contrast material should be delayed until the results of a hemoglobin electrophoresis are available.

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#### **Acute Bacterial Sinusitis**

Linda M. Frazier, M.D. and G. Ralph Corey, M.D.

• Think of it when a "cold" suddenly gets worse.

DURING the winter months, physicians see many patients with upper respiratory infections. Most of these patients will get better on their own but in some cases symptoms may linger or reappear after an initial improvement. Acute bacterial sinusitis should be suspected when fever or other symptoms recur or worsen following an upper respiratory infection. The diagnosis is easily confirmed radiographically, but the physician must first suspect bacterial sinusitis and order sinus radiographs. If left untreated, bacterial sinusitis can lead to serious complications, including osteomyelitis, orbital cellulitis or meningitis.¹ We recently have cared for four patients who developed acute bacterial sinusitis following viral infections. In doing so, we learned several things about sinusitis that we would like to share.

Our first patient was a 47-year-old woman who was in good health until she developed fever (38.3°C), chills, myalgias, headache and stuffy nose. Her symptoms improved over the next week only to be replaced by increasing right frontal headache, unrelieved by aspirin. She continued to work. She did not appear acutely ill; there was no fever, sinus tenderness, proptosis, periorbital swelling or nuchal rigidity. Radiographs demonstrated airfluid levels in the right frontal and both maxillary sinuses; the left frontal sinus was completely opacified. She was treated with Ceclor (cefaclor) 500 mg by mouth three times per day and Afrin (oxymetazoline hydrochloride) nasal spray for five days. Her symptoms resolved promptly. She was then given Ceclor 250 mg by mouth three times per day to complete a 14-day course.

Our second patient was a 26-year-old woman who had a lingering "cold" for about five weeks when she developed a cough with green sputum. She was given erythromycin 250 mg by mouth four times a day. One week later she returned with persistent nocturnal fever to 39°C. She continued to work. She had a mild frontal headache and slight nasal congestion. She appeared well; temperature was 37°C; the nasal mucosa was erythematous with a thin mucopurulent discharge on the left. There was no swelling or tenderness over the sinuses. Radiographs showed air-fluid levels in the right frontal and both maxillary sinuses. Her symptoms resolved within a few days during treatment with Ceclor and Afrin nasal spray.

Both these patients developed acute sinusitis a week or so after an upper respiratory infection. The paranasal sinuses are lined with ciliated columnar epithelium. Viral

infection disrupts mucociliary transport, leading to bacterial superinfection in accumulated secretions. Sinus drainage can be further inhibited by mucosal edema which causes narrowing or obstruction at the sino-nasal meatus. Noninfectious conditions that predispose to acute sinusitis include septal deviation, foreign bodies, tumors or polyps due to allergic rhinitis or chronic sinusitis.<sup>2</sup>

Approximately 0.05% of patients with upper respiratory infections develop acute bacterial sinusitis. Clinical signs and symptoms can heighten suspicion of this diagnosis. In our first patient, we suspected acute sinusitis because of worsening unilateral frontal headaches following a viral illness. In the second instance, we pursued the diagnosis of sinusitis because of persistent fever despite resolving symptoms of bronchitis.

How good are clinical signs and symptoms in predicting which patients have acute bacterial sinusitis? The sensitivity and specificity of history and physical examination data are usually not precisely known. One prospective study in 164 patients was performed to determine whether certain symptoms and signs were correlated with radiographically-proven acute maxillary sinusitis.3 The patients were recruited from an otolaryngology clinic and had sinus radiographs if they or their doctors thought they might have acute sinusitis. Acute sinusitis (mucus membrane thickening more than 6 mm or complete opacity) was found radiographically in 22% of patients. Patients with acute sinusitis by x-ray had the following clinical features more frequently than patients with normal sinus radiographs: preceding upper respiratory infection (90% vs 67%), purulent nasal discharge (75% vs 44%), decreased sense of smell (75% vs 40%), pus in the middle or inferior meatus (30% vs 3%) and fever exceeding 38°C (28% vs 2%).3

This study shows that certain signs and symptoms tend to be associated with acute sinusitis. The problem is that many patients with normal sinus radiographs may also have these clinical features. While no sign or symptom will make the diagnosis conclusively, using all the clinical features together will help determine when to suspect acute sinusitis.

Why is this important? Sinus radiographs are expensive (\$107.00 at our institution). One would like to order radiographs primarily when patient management would be improved by knowing the diagnosis with certainty. Patients in whom acute sinusitis is probable (those with a preceding upper respiratory infection, a purulent nasal discharge and fever who are not improving as expected) can often be treated with antibiotics empirically. Patients in whom acute sinusitis is improbable (those who have no

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Table 1
Charges at three local pharmacies for a ten-day course of antiblotics potentially effective in acute bacterial sinusitis.

Antimicrobial	Dally Dose		Pharmacy	
Agent	(mg)	Α	В	С
Ampicillin	2,000	\$8.26	\$7.67	\$11.49
Amoxicillin	1,500	\$8.93	\$9.97	\$10.65
Tetracycline	2,000	\$4.06	\$4.58	\$ 6.45
Doxycycline Doxycycline	200	\$15.01	\$16.90	\$ 8.89
Trimethoprim-			Ψ10.50	Ψ 0.05
sulfamethoxazole	320/1,600	\$ 8.60	\$ 8.28	\$ 8.39
Erythromycin	2,000	\$ 8.09	\$14.63	\$10.19
Ceclor*	2,000	\$73.13	\$93.25	\$89.02
Keflex†	2,000	\$34.40	\$53.44	\$57.29
Augmentin‡	1,500	\$30.92	\$40.01	\$36.37
Clindamycin¶	600	\$29.00	\$40.10	\$36.25

\*Cefaclor

† Cephalexin ‡ Amoxicillin/potassium clavulanate

Not recommended as a single agent.

suggestive symptoms or signs) may be followed without antibiotics. Radiographs could be reserved for patients in whom the diagnosis is unsure and for patients who fail to respond to conventional therapy, who appear acutely ill or who develop complications. The diagnosis may be particularly difficult to make clinically in patients with chronic sinusitis because these patients have longstanding fluctuating sinus symptoms.

Sinus transillumination can also aid in diagnosis. In a completely darkened room, light applied to the patient's cheek will normally illuminate the roof of the mouth. In patients with previously normal sinuses, complete opacity on sinus transillumination is strong evidence for the presence of active infection. Normal light transillumination is good evidence that no infection is present, but intermediate or "dull" transillumination is of limited diagnostic value.

Another consideration in making the diagnosis of acute sinusitis is that sinus radiographs are somewhat difficult to read. It is a good idea for physicians without expertise in their interpretation to go over the films with a radiologist. One of us initially thought our second patient's sinus radiographs were normal, but the radiologist pointed out three air-fluid levels.

Accurate microbiologic cultures are obtained by sinus puncture, but this procedure is not indicated in routine clinical practice. The most common pathogens in acute sinusitis are Streptococcus pneumoniae, Haemophilus influenzae, and Staphylococcus aureus. Haemophilus influenzae predominates in children. In adults, Haemophilus species are present in about 26% of patients and Streptococcus pneumoniae in about 36%. Cultures may show multiple organisms and anaerobic infections are present in up to 10%. Staphylococcus aureus is found in up to 8% of cases, but it is responsible for about 50% of orbital and intracranial complications.

No single antibiotic is effective against all possible pathogens. Ampicillin, tetracycline and trimethoprim-sulfamethoxazole are effective against *Haemophilus*, *Streptococcus* and some *Staphylococcus* species. Erythromycin may be effective against *Streptococcus* and *Staph-*

ylococcus, but some *Haemophilus* and *Staphylococcus* species may be erythromycin-resistant. Ceclor and Augmentin (amoxicillin/potassium clavulanate) provide antibacterial activity against the three most common pathogens, but Ceclor may not be effective against anaerobes. Penicillin or clindamycin provides good anaerobe coverage, while chloramphenicol has excellent activity against *Haemophilus*.

Cost is a major consideration when choosing antibiotic therapy. Ampicillin, tetracycline and trimethoprim-sulfamethoxazole are very cheap compared with newer agents such as Ceclor and Augmentin which are not available in generic preparations (table 1). We used Ceclor in our first two patients but now feel that it is not the best drug for initial therapy of acute sinusitis. In uncomplicated cases, ampicillin, tetracycline or trimethoprim-sulfamethoxazole may be used empirically. Clinical response is usually good and these drugs can be purchased at a fraction of the cost of Ceclor. Augmentin, at half the cost of Ceclor, provides broader antibacterial activity against the major pathogens found in acute sinusitis. In patients who are severely ill or in whom intracranial complications are suspected, sinus cultures may be needed to guide therapy.

Nasal decongestants are an important component of therapy in acute bacterial sinusitis. Neosynephrine nose drops, ½ or ½%, or Afrin spray should be applied several times per day during the first five days of therapy to decrease mucosal edema at the meatus and promote sinus drainage. Sinus lavage may be required. Antihistamines should not be used because they thicken purulent sinus fluid and impair drainage. Because of tachyphylaxis, nasal decongestants should not be used chronically.

Symptoms of acute maxillary sinusitis should resolve within five days when treatment with appropriate antibiotics and decongestants is begun.<sup>4</sup> Resolution of radiologic abnormalities may take two weeks or longer.<sup>4</sup> Severe or worsening symptoms may indicate that a drainage procedure such as the Caldwell-Luc operation or frontal sinus trephinement must be performed. A resistant organism may be present. Rarely, a fungal infection or tumor may be found.<sup>5</sup> Fungal infections are found primarily in patients

with diabetes mellitus or immunosuppression. Persistent symptoms may also indicate that complications have occurred, such as osteomyelitis, orbital abscess or intracranial infection. Intracranial complications were suspected in our third patient and did occur in our fourth patient.

Our third patient was a 28-year-old woman who was in good health until she developed a dry cough. After four weeks she also developed headache, runny nose, pharyngitis, left ear pain and pain in her upper teeth. Temperature was 36.8°C; the left tympanic membrane was red and bulging; the pharynx was erythematous with shotty cervical adenopathy; the chest was clear. She was treated with erythromycin 250 mg by mouth three times per day and Afrin nasal spray. Two days later she returned complaining of severe pain "all over her face," nocturnal fever, nasal discharge, nausea and vomiting. The pain was worse over the right orbit. She appeared acutely ill; temperature was 36.6°C; extraocular movements were intact. There was purulent nasal discharge but no orbital cellulitis, proptosis or meningismus. Sinus radiographs revealed pansinusitis with opacification of the right maxillary sinus and air-fluid levels in the frontal sinuses.

She was hospitalized for treatment and observation to determine if a drainage procedure would be required. She was given Cefadyl (cephapirin) 4 g per day intravenously. She was never febrile. Culture of nasal discharge grew *Haemophilus influenzae*. A computed tomographic scan of the head was done because of continued nausea and vomiting; there was no intracranial involvement. Vomiting was attributed to narcotic analgesics. Symptoms improved within five days. Antibiotics were then changed to Keflex 500 mg by mouth four times per day; she was treated for a total of three weeks with complete recovery.

This patient developed acute bacterial sinusitis following a prolonged upper respiratory infection. The diagnosis was first suspected because her upper respiratory symptoms got worse instead of better, and she was initially treated empirically with erythromycin. When she did not respond, sinus radiographs were used to confirm the diagnosis and sinus cultures were used to direct antimicrobial therapy. We thought she was at risk for orbital or intracranial infection because she appeared toxic, had severe periorbital pain and had persistent fever while on antibiotics. We were concerned that her nausea and vomiting could have been a sign of increased intracranial pressure due to a brain abscess. This was ruled out and she did well with three weeks of high dose antibiotic therapy.

Our fourth patient was a 16-year-old boy who presented in status epilepticus. He had been well until he developed rhinitis and nasal congestion after going swimming. Over the next 24 hours he had malaise, nausea, vomiting and lethargy, and then noted the onset of fever and swelling around the left eye. Three days after the illness began he had four grand mal seizures. On admission, he was combative and disoriented. His temperature was 39°C. There was left proptosis, chemosis and periorbital edema; the supra-orbital notch was tender and there was loss of function in cranial nerves III, IV and VI on the left. There was purulent discharge from the left nostril. WBC count was 15,300 with a left shift; lumbar puncture showed 26 white cells/mm³ (74% polymorphonuclear leukocytes); a com-

puted tomographic scan of the head was negative. Sinus radiographs showed pansinusitis with most pronounced involvement of the ethmoid and frontal sinuses. The patient was treated with nafcillin and chloramphenicol intravenously and had surgical drainage of the ethmoid and frontal sinuses. Spinal fluid cultures were negative; intraoperative sinus cultures grew *Staphylococcus aureus*. Temperature and mental status returned to normal within 48 hours, and he recovered completely.

This patient developed acute sinusitis following the onset of upper respiratory infection symptoms; swimming was also a risk factor for acute sinusitis.<sup>2</sup> He was felt to have orbital cellulitis resulting from extension of ethmoid sinusitis. The seizures were felt to be caused by a parameningeal focus of infection with a component of cerebritis. The superior orbital fissure was involved, causing cranial nerve impairment.

During acute bacterial infections, the inflammatory process may invade the surrounding structures of any sinus, but maxillary sinus infections spread least frequently. As in this patient, ethmoid sinusitis may lead to orbital cellulitis and abscess. <sup>1, 2</sup> Cavernous sinus thrombosis may then develop and is often fatal. Sphenoid sinusitis may spread to the superior orbital fissure, involving the third, fourth and sixth cranial nerves. Frontal sinus infections may lead to osteomyelitis with cellulitis of the scalp and upper eyelid on the affected side (Pott's puffy tumor). <sup>1, 2</sup> Frontal lobe abscess may occur if frontal sinusitis spreads posteriorly.

In summary, during the "cold and flu" season, there may be a great deal of overlap in presenting signs and symptoms of rhinitis and bacterial sinusitis. Acute sinusitis should be suspected in patients with a preceding upper respiratory infection, purulent nasal discharge, decreased sense of smell, fever or opaque sinus transillumination. When the diagnosis is uncertain, the presence of acute sinusitis can be confirmed by sinus radiographs. Appropriate antibiotic and decongestant therapy should then bring about marked improvement within five days. Ampicillin, amoxicillin, trimethoprim-sulfamethoxazole, tetracycline or Augmentin are acceptable as initial therapy. Severe symptoms or failure to improve may indicate that a drainage procedure is necessary. Patients should be watched for signs of orbital or central nervous system complications.

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### Laboratory Tests in the Diagnosis of Vitamin B<sub>12</sub> (Cobalamin) Deficiency

David B. Matchar, M.D., and John R. Feussner, M.D.

 Editor's Note: This is a scholarly paper bringing us up to date on an important subject. Because of the controversy in interpreting the use of serum B<sub>12</sub> levels the editor has allowed a longer bibliography than customary.

The editor is somewhat perplexed. The question at issue is whether low levels of  $B_{12}$  in elderly persons mean that some cells are functioning poorly because of  $B_{12}$  deficiency and whether raising the levels of  $B_{12}$  will result in normal function. The editor would be more comfortable if our colleagues would study the isolated cells from their patients with low  $B_{12}$  levels and show that addition of  $B_{12}$  improved their function. The problem is a little like that of osteoporosis. Our scientific colleagues tell us that putting a little calcium in bones will make them young. We old folk watching our skin bruise, our muscles weaken, our rate of voiding decrease, our guts fill with gas, know that this simple answer to osteoporosis must be wrong.

THE diagnosis of vitamin B<sub>12</sub> (cobalamin) deficiency 1 continues to frustrate the clinician. This serious and potentially treatable disorder presents many faces. The diagnosis of deficiency may be suspected on the basis of a particular finding such as macrocytic anemia, dementia, peripheral neuropathy, or in light of a known condition such as gastrectomy, ileal resection or Crohn's disease. Because of the association of pernicious anemia with other autoimmune disorders, it may be suspected in patients with Hashimoto's thyroiditis, hypothyroidism or vitiligo. Not only is B<sub>12</sub> deficiency a concern for the physician faced with a patient presenting with a suspicious condition, it also constitutes a significant public health concern. Although the exact prevalence of true (tissue) B<sub>12</sub> deficiency is unknown, it is not rare. At the Mayo Clinic, 1.5% of a group of study volunteers believed to be healthy had evidence of true deficiency.2 This proportion may be as high as 9% in high risk elderly populations.3 Despite the apparent magnitude of the problem of vitamin B<sub>12</sub> deficiency, there is no simple procedure that distinguishes those people with true deficiency. A brief review of the tests for vitamin B<sub>12</sub> deficiency underscores the fact that diagnosis is not a simple matter.

#### The Serum B<sub>12</sub> Assay

For the past 30 years, the serum B<sub>12</sub> assay has been used with increasing frequency. Despite this, its sensitivity and specificity have been the source of doubt and confusion<sup>4</sup>

and the B<sub>12</sub> assay result is often disregarded by clinicians, 5, 6 In 1956 an improved microbiologic assay for B<sub>12</sub> was developed by Hutner, Bach and Ross. 7 In addition to false results due to drug effects, 8 this test was not uniformly available. The radiodilution immunoassay was introduced in 1965 by Gottlieb et al. 9 Cooper and Whitehead 10 and Kolhouse 11 reported in 1978 that impurities in the binding proteins used in the assay resulted in false negative results (normal test results in deficient patients) through the inadvertent identification of inactive B<sub>12</sub> analogs. Reliance on the assay alone was associated with cases of delayed or misdiagnosis and resultant mortality and morbidity. 12, 13

Recently assays have been introduced that use purified intrinsic factor or a binding protein mix in which B<sub>12</sub> analog sites are blocked. These assays appear to be as sensitive as microbiologic assays14 and have apparently minimized false negative results. Unfortunately, the new assays may be replacing a false-negative problem with a false-positive problem (abnormal test results in normal patients). Indeed the new B<sub>12</sub> assays with improved sensitivity have resulted in a greater frequency of low values, about 10-20% of all assays performed.15 On noting this Schilling et al questioned whether the bulk of the "positive" results actually represent clinically important deficiencies. More extensive evaluation of selected patients with low serum B<sub>12</sub> levels by microbiologic assay16, 17 and by radiodilution assay 6, 18, 19 suggests that as many as two-thirds of patients with low  $B_{12}$  assay results have no obvious deficiency.

#### The Schilling Test

This test is performed by giving the patient a dose of

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labeled B<sub>12</sub> orally, followed by a flushing dose of "cold" B<sub>12</sub> intramuscularly. If the radioactive B<sub>12</sub> has been absorbed appropriately, the flushing dose of intramuscular  $B_{12}$  will displace the radioactive  $B_{12}$  from its binding sites and cause urinary excretion of the radioactive B<sub>12</sub>. From the time the radioactive  $B_{12}$  is given, a 24-hour urine collection is begun to assess the percentage of excreted radioactive B<sub>12</sub> Excretion of at least 7% of the orally administered B<sub>12</sub> implies normal mechanisms for absorption of B<sub>12</sub>. A normal result is strong indirect evidence that a patient is not deficient, as few patients with B<sub>12</sub> deficiency have normal B<sub>12</sub> absorption.<sup>20</sup> Falsely normal results have been attributed to dietary deficiency (rare in non vegetarians) or fecal contamination of the urine specimen or incorrect use of the newer dual isotope Schilling tests.23 It has also been suggested that some patients may be able to absorb the crystalline form of B<sub>12</sub> given in the Schilling test, but not food-bound B<sub>12</sub>.<sup>21</sup> The significance of this phenomenon remains controversial.22

An abnormal Schilling test suggests inadequate absorption arising from either lack of intrinsic factor or small bowel disease with malabsorption. To differentiate the cause of an abnormal test, the Schilling test is repeated with the addition of oral intrinsic factor. If the test remains abnormal, this indicates small bowel malabsorption or ileal disease. Falsely abnormal results may occur with inadequate urine collections or reduced glomerular filtration rate.

#### Bone Marrow Examination

Rapidly proliferating hematopoietic tissues are affected early in the course of vitamin  $B_{12}$  deficiency. The imbalance in the coordinated relationship among DNA, RNA and protein synthesis is reflected in the bone marrow as megaloblastosis. Red blood cell precursors are large, and there is asynchrony between the cytoplasm which matures normally and the nucleus which continues to appear immature. Interpretation of the marrow specimen may be difficult if the patient has received any  $B_{12}$  (for example during the Schilling test), as the bone marrow can assume a more normoblastic picture in as little as 12-24 hours. A frankly megaloblastic marrow may occur also in patients without  $B_{12}$  deficiency, most commonly in folate deficiency.

#### The Deoxyuridine Suppression Test

The deoxyuridine suppression test (DST) devised by Killman<sup>24</sup> is a direct measure of tissue deficiency. The test is performed on the bone marrow cells, and an abnormal result essentially reflects a defect in the methylation of deoxyuridylic acid to thymidylic acid. If added  $B_{12}$  normalizes the DST then a deficiency in vitamin  $B_{12}$  can be inferred. This technique does not provide the simple and practical test needed in a general clinical setting.

#### The Methylmalonic Acid Assay

The isomerization of methylmalonic acid (MMA) to succinic acid requires adenosylcobalamin, and absence of this form of vitamin B<sub>12</sub> results in increased urinary excretion of MMA. Although older assays for MMA have been unreliable for establishing the diagnosis of B<sub>12</sub> deficiency,<sup>25</sup> the use of a gas chromatographic/mass spectro-

metric method has resulted in an improved test.<sup>26</sup> The MMA assay appears to be a promising candidate for a more effective screening test, but its accuracy has not been established. While we are gaining experience with this new assay at Duke,<sup>27</sup> it is not generally available for clinical use.

#### Therapeutic Trial of Vitamin B<sub>12</sub>

Prior to the development of laboratory tests, physicians established the diagnosis of vitamin  $B_{12}$  deficiency by observing the reversal of certain clinical findings with vitamin  $B_{12}$  replacement. There are several problems with this approach. Unless a readily reversible abnormality such as a low hemoglobin can be monitored, the assessment of a therapeutic trial is likely to be difficult. Many index symptoms or signs may be difficult to monitor accurately or may not change at all, such as peripheral neuropathy or dementia.

#### **Practical Concerns**

We are now faced with the following uncomfortable facts. About 15% of the large number of patients with a reasonable indication for having a serum  $B_{12}$  level will have low values. Perhaps two-thirds of these patients will in fact have no definite evidence of deficiency. Although we may be tempted to treat all patients with low serum  $B_{12}$  levels with parenteral  $B_{12}$ , this would be both a scientifically unsatisfying and a very expensive alternative to accurate diagnosis, especially considering that treatment is life-long.

In lieu of the perfect diagnostic test, we would like to make the following practical suggestions regarding an approach to the diagnosis of vitamin B<sub>12</sub> deficiency (figure 1). All patients with suspected deficiency should have a serum B<sub>12</sub> assay performed. An abnormal result should not be considered diagnostic. All patients with low B<sub>12</sub> assay results should have a Schilling test performed. Patients with an abnormal Schilling test should be examined for the cause of the malabsorption, treated with 1,000 µg of parenteral B<sub>12</sub> daily for four to seven days and 1,000 µg monthly thereafter, and followed for evidence of improvement. Although alternate treatment regimens are under study,28 it is not currently recommended to extend the interval between maintenance injections beyond two months as less frequent treatment has not been proven to be safe. Patients with a normal Schilling test without evidence of fecal contamination of the urine sample (a cause of falsely normal results) probably do not have vitamin B<sub>12</sub> deficiency. However, if the clinician is worried about the patient and confused about the discordant laboratory results, the patient may be treated with 5 µg of oral cyanocobalamin daily (without folate) and followed for evidence of hematologic improvement. If the patient has no peripheral blood abnormalities to monitor, the alternatives are to observe without treatment or to obtain additional studies such as bone marrow, MMA or DST. Meanwhile one should not delay important diagnostic evaluation of the index signs or symptoms.

In the future there may be a simple test or combination of tests that would accurately distinguish vitamin B<sub>12</sub> deficient patients from those who are non-deficient. Until

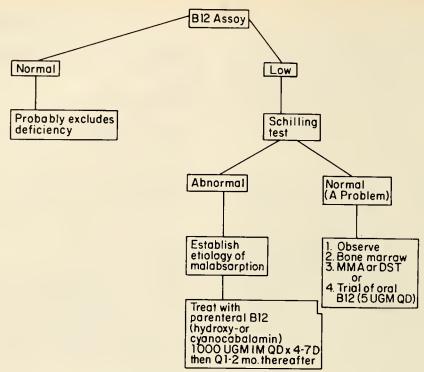


Figure 1. Evaluation of the suspected B<sub>12</sub>-deficient patient.

that time we will continue to scratch our heads, carefully observe the patient and discard the confusing B<sub>12</sub> assay result.

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The Logical Path to Compliance

#### BETA-BLOCK OR

Recommended Step-1 therapy hypertension con

#### DIURETIC

The addition of a diuretic enhances the efficacy of the beta-blocker.

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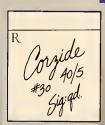
### CONTROL, COMPLIANCE, CONVENIENCE

When hypertension control is complicated by the need for a beta-blocker plus a thiazide, CORZIDE® simplifies patient compliance with reliable once-a-day dosing in a single tablet.

### CORZIDE

(nadolol-bendroflumethiazide tablets)

Makes good sense





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"Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure The 1984 report of the Joint National Committee on Detection, Evaluation and Treatment of High Blood Pressure. Arch Intern Med 144:1045-1057, 1984.

Please see brief summary of prescribing information on following page

# CORZIDE

(nadolol-bendroflumethiazide tablets)

CORZIDE® 40/5 CORZIDE® 80/5

Nadolol-Bendroflumethiezide Tableta

DESCRIPTION: CORZIDE (Nadoloi-Bendroffumethiazide Tablets) for oral administration combines two antihyperiensive agents. CORGARD® (nadoloi), a nonselective bela-adrenergic blocking agent, and NATURETIN® (bendroffumerhiazide), a thiazide diuretic-antihyperiensive Formulations. 40 mg and 80 mg nadoloi per tablet combined with 5 mg bendroffuncers.

CONTRAINDICATIONS: Nadolol — Bronchial asthma, sinus bradycardia and greater than first degree conduction block, cardiogenic shock, and overt cardiac failure (see WARNINGS) Bendroflumethiazide — Anuria, and in those with previous hypersensitivity to bendroflu-methiazide or other sulfonamide-derived drugs.

methiazide or other sulfonamide-genved drugs.

WARNINGS: Nadold — Cardiac Falliure — Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta-blockade may precipitate more severe failure. Although beta-blockers should be avoided in overt congestive heart failure, if necessary, they can be used with caution in patients with a history of failure who are well-compensated, usually with digitalis and diurertics. Beta-adrenergic blocking agents do not abotish the inotropic action of digitalis on heart muscle. IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta-blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, digitalize and/or give diuretics, and closely observe response, or discontinue nadolol (gradually, if possible)

Execerbation of Ischemic Heart Disease Following Abrupt Withdrawal—
Hypersensitivity to catecholamines has been observed in patients withdrawn from
beta-blocker therapy, exacerbation of angina and, in some cases, myocardial infarction have occurred after abrupt discontinuation of such therapy. When discontinuary
fromic use of nadolo, particularly in patients with schemic heart disease, gradually
reduce dosage over a 1- to 2-week period and carefully monitor the patient.
Beinstitute hadolol promptly (at least temporarily) and take other measures appropriate for management of unstable angina if angina markedly worsens or acute
coronary insufficiency develops. Warn patients not to interrupt or discontinue
therapy without physician's advice. Because coronary artery disease is common
and may be unrecognized, it may be prudent not to discontinue nadolol therapy
abruptly even in patients treated only for hypertension.

Nonallergic Bronchospesm (e.g., chronic bronchils, emphysems) — PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD IN GENERAL NOT RECEIVE BETA-BLOCKERS. Administer nadolo with caution since it may block bronchodiation produced by endogenous or exogenous catecholamine stimulation of beta, receptors Mejor Surgery — Because beta blockade impairs the ability of the heart to respond to reflex stimuli and may increase the risks of general anesthesia and surgical procedures, resulting in protracted hypotension or low cardiac output, if has generally been suggested that such therapy should be withdrawn several days prior to surgery Recognition of the increased sensitivity to catecholamines of patients recently withdrawn from beta-blocker therapy, however, has made this recommendation controversial. If possible, withdraw beta-blockers well before surgery takes place, in emergency surgery, inform the anesthesiologist that the patient is on beta-blocker therapy. Use of beta-receptor agonists such as isoproferency, dopamine, dobutamine, or levanterenol can reverse the effects of nadolof Difficulty in restarting and maintaining the heart beat has also been reported with beta-adrenergic receptor blocking agents. Dibetes and Hypogly-cemie — Beta-adrenergic blockade may prevent the appearance of premonitority signs and symptoms (e.g., factly-cardia and blood pressure changes) of acute hypoglycemia. This is especially important with lablie diabetics. Beta-blockade also reduces release of insulin in reformation of the properties of the prop

Introductions:

Bendroflumethlazide — Use with caution in severe renal disease. In patients with renal disease, azotemia may be precipitated. With impaired renal function, effects of the drug may be cumulative. Use with caution in impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic coma. Sensitivity reactions may occur in patients with a history of altergy or bronchial asthma. Possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

PRECAUTIONS: General — Nadolot — Use with caution in patients with impaired hepatic or renal function (see DOSAGE AND ADMINISTRATION).

or renal function (see DOSAGE AND ADMINISTRATION)

Bendroflumethiazide — At appropriate intervals, perform serum electrolytes determination to detect possible electrolyte imbalance warring signs of which are dryness of mouth, thirst, weakness, fethatgy, drowsiness, restlessness, muscle pains or cramps, muscular fatigue, hypotension, oliguria, tachycardia, and G.I. distributances such as nausea and vomiting Observe patients for clinical signs of fluid or electrolyte imbalance; namely, hyponaternia, hypochalernia aserum and urine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Drugs such as digitalis may influence serum electrolytes hypokalemia may develop, especially with birsk diurests, in presence of severe cirrhosis, interference with adequate oral electrolyte intake will also contribute to hypokalemia. Response of the heart to loxic effects of digitalis can be exaggerated with hypokalemia. Use potassium supplements such as high potassium foods to avoid or treat hypokalemia. Any chiloride deficit is generally mild and usually does not require specific therapy except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponatremia may occur in edematous patients in hot weather, appropriate therapy is water restriction rather than salt administration except in rate instances when the hyponatremia is life threatening in actual salt depletion, appropriate replacement is the therapy of choice.

when the hyponatremia is life threatening in actual sair depletion, appropriate repractmentable therapy of choice. Hyperuricemia may occur or frank gout may be precipitated in certain thiazide-treated patients. Latent diabeles mellitus may become manifest during hiazide therapy. Antihypertensive effects of bendroflumethiazide may be enhanced in the postsympathectomy patient. Careful reapprissal of therapy and consideration given to withholding or stopping diuretic inerapy is necessary if rising nonprotein nitrogen or BUN (indicative of progressive renal impairment) occurs. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Thiazides decrease calcium excretion. Pathologic changes in parathyroid gland with hypercalcemia and hypophosphatemia have been occasionally observed with prolonged inerapy. Common complications of hyperparathyroidism have not been seen.

Information for Patients — Warn patients, especially those with evidence of coronary artery insufficiency, against interruption or discontinuation of nadolol without physician's advice. Although cardiac failure rarely occurs in properly selected patients, advise patients being treated with beta-adrenergic blocking agents to consult physician at the first sign or symptom of impending failure. Advise patients of proper course if dose inadvertently missed.

of impending failure. Advise patients of proper course if dose madvertently missed.

Laboratory Testa. — Regularly monitor serum and urine electrolyte levels (see WARNINGS, Bendroflumethrazide, and PRECAUTIONS, General, Bendroflumethrazide).

Drug Interactions. — Nadolol. — When administered concurrently the following drugs may interact with beta-adrenergic blocking agents. Anesthetics, general.— exaggeration of anesthetic-induced hypotension (see WARNINGS, Nadolol, Major Surgery). Antidiabetic drugs (oral agents and insulin). — hypoglycemia or hyperglycemia, adjust antidiabetic drugs dosage accordingly (see WARNINGS, Nadolol, Diabetes and Hypoglycemia). Catechol-maine depleting drugs (e.g., reserpins). — additive effect, monitor closely for evidence of hypotension and/or excessive bradycardia.

Bendroflumethlazida. — When administered concurrently the following drugs may interact with thiazide diuretics. Atcohol, barbitureties, or narcolles. — may potentiate orthostatic hypotension. Antidiabetic drugs (oral agants and insulin). — thiazide-induced hyperglycemia may require adjustment of antidiabetic drug dosage. Other antihypertansive drugs.— additive or potentiated effect. Corticosterolds, ACTH. — intensihed electrolyte depletion, particularly hypokalemia. Ganglionic or peripheral edirangic blocking drug. — potentiated effect. Presinashetic and snesthetic agents. — effects may be potentiated adjust dosage accordingly Pressor amines (e.g., norepinephrine) — possible decrease response but not sufficient to preclude their use. Skelatal muscle relaxants, nondepolarizing (e.g., tubocurarine). — possible increased response.

Drugflaboratory Test Interactions. — Discontinue thiazides before tests for parathyroid function (see PRECAUTIONS, General, Bendroffumethrazide).

Carcinogeneals, Mutaganesis, impairment of Fertility — Nadolol — In 1 to 2 years oral toxicologic studies in mice, studies in adolgs, adolod did not produce significant toxice effects - 2-year oral carcinogenic studies in rats and mice, hadolod did not produce significant toxice effects or plastic, or nonneopelastic pathologic lesions. Bendroflumethlazide — Long-term studies in animals have not bedeen performed

animals have not been performed.

Pregnancy — Terstogenic Effects — Nadolof — Category C. In animal reproduction studies with nadolof, evidence of embryo- and fetotoxicity was found in rabbits, but not in rats or hamsters, at doses 5 to 10 times greater (on a mg/kg basis) han the maximum indicated human gose, no teratogenic potential was seen in any of these species. There are no well-controlled studies in pregnant women, therefore, use nadoloi in pregnant women only if potential benefit justifies potential risk to the fetus. Bendroffumethiazide — Category C. Animal reproduction studies have not been conducted. This drug's effect on the fetus when administered to a pregnant woman or its effect on reproductive capacity is not known. Bendroffumethiazide should be given to a pregnant woman only if clearly needed. Nontarstogenic Effects — Since thiazides cross the placental barrier and appear in cord blood, weigh anticipated benefit of the drug in pregnant women against possible hazards to the fetus; these hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other reactions which have occurred in adults.

Nursing Mothers — Both nadolol and bendroflumethiazide are excreted in human entite.

Nursing Mothers — Both nadotol and bendroflumethiazide are excreted in human milk Because of the potential for serious adverse reactions in nursing inflants either discontinue tentapy, taking into account the importance of CORZIDE (Nadolol-Bendroflumethiazide Tablets) to the mother.

Pedietric Use - Safety and effectiveness in children have not been established

Bendröftlumethiazide Tablets) to the möhter.

Pedietric Use — Safety and etlectiveness in children have not been established.

ADVERSE REACTIONS: Nadolol — Most adverse effects have been mild and transent and have rarely required hadold withdrawal. Cardiovaeculer — Bradycardia with heart rates of less than 60 beats per minute occurs commonly, and heart rates below 40 beats per minute and/or symptomatic bradycardia were seen in about 2 of 100 patients. Symptoms of peripheral vascular insufficiency, usually of the Rayhaud type, have occurred in approximately 2 of 100 patients. Cardiac lautive, hypotension, and hyphmiconduction disturbances have each occurred in about 1 of 100 patients. Single instances of first degree and hird degree heart block have been reported, intensification of AV block is a known effect of betablockers (see also CONTRAINDICATIONS, WARNINGS, and PRECAUTIONS). Central Nervous System — Dizzness or fatigue reported in approximately 2 of 100 patients, paresthesias, sedation, and change in behavior reported in approximately 6 of 1000 patients. Respiretory — Bronchospasm reported in approximately 1 of 1000 patients. See CONTRAINDICATIONS and WARNINGS). Gastrointestinal — Nausea, duarrhea, abdominal discombort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. Miscellenaoue — Each of the following reported in 1 to 5 of 1000 patients. See CONTRAINDICATIONS and WARNINGS, Gastrointestinal — Nausea, duarrhea, abdominal discombort, constipation, vomiting, indigestion, anorexia, bloating, and flatulence each reported in 1 to 5 of 1000 patients. Miscellenaoue — Each of the following reported in 1 to 5 of 1000 patients with the parent of the patients of the patients of the patients with the patients of the patients. Patients were substituted vision. Although relationship to drug usage is not clear, sleep disturbances have been reported. The coulomucocutaneous syndrome characterized by disorientation for time and place, short-term memory loss;

erythematous rash, arterial insufficiency

Bandrollumethiazide — GastroIntestinal System — anorexia, gastric irrilation, nausea,
vomiting, cramping, diarrhea, constipation, jaundice (intrahepatic cholestatic jaundice), pancreatists. Central Nervous System — duziness, vertigo, paresthesia, headache, xanthopsia. Hemetologic — leukopenia, agranulocytosis, thrombocytopenia, aplastic anemia.

Dermatologic-Hypersensitillity — purpura, photosensitivity, rash, urticaria, necrotzing,
angitis (vasculitis, cutaneous vasculitis). Cardiovascular — orthostatic hypotension may
occur Other — hyperglycemia, glycosuria, occasional metabolic acidosis in diabetics,
hyperuricemia, allergic glomerulonephritis, muscle spasm, weakness, restlessness. Whenever adverse reactions ser moderate or severe illustrate dispasm, build he zadverdent therawing. ever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy

OVERDOSAGE: Nadolol may cause excessive bradycardia, cardiac failure, hypotension, or bronchospasm if overdosed. Overdosage of thiazides may cause lethargy, which may progress to coma within a lew hours, with minimal depression of respiration and cardiovascular function and without evidence of serum electrolyte changes or dehydration. Gastrointestinal virilation and hypermotility may occur. Transitory increase in BUN and serum electrolyte changes may occur, especially in patients with renal impairment.

changes may occur, especially in patients with renal impairment
Treatmant — Nadolot can be removed from the general circulation by hemodialysis. In determining duration of corrective theraby, take note of the long duration of the effect of nadolot. In addition to gastric lavage, employ the following measures, as appropriate Exceleive Bredycardla — Administer alropine (0.25 to 1.0 mg). If there is no response to vagal blockade, administer isoproferenol cautiously. Cerdiac Fellure — Administer a digitalis glycoside and diuretic. If has been reported that glucagon may also be useful in this situation Hypotenelon — Administer vasopressors, e.g., apinephrine or levarterenol. (There is evidence that epinephrine may be the drug of choice) Bronchoapeam — Administer abeta; sumulating agent and/or a theophylline derivative. Support of Come — Supportive therapy as warranted. Gestrointestinel Effects — Symptomatic treatment as needed BUN and/or Serum Efactoryle Abnormalities — Institute supportive measures as required to maintain hydration, electrolyte balance, respiration, and cardiovascular and renal function.

DOSAGE AND ADMINISTRATION: DOSAGE MIRST BE INDIVIDIALIZED. Patients with

DOSAGE AND ADMINISTRATION: DOSAGE MUST BE INDIVIDUALIZED. Patients with renal failure require adjustment in dosing interval, see package insert for dosage in these patients

Consult peckage insert before prescribing CORZIDE (Nedolof-Bendroflumethiazide Tablets).

HOW SUPPLIED: Available as scored tablets containing 40 mg nadolol combined with 5 mg ben-droflumethiazide and 80 mg nadolol combined with 5 mg bendroflumethiazide in bottles of 100.

#### A Summary Analysis of the North Carolina Trauma and Burn Study

H. J. Proctor, M.D., and Tom Harmelink

THE striking improvement in mortality and morbidity achieved in Vietnam, along with the early successes of certain systems such as that pioneered by R. Adams Cowley in Maryland, alerted the public to the benefits of a systematic approach to trauma care. The Federal Emergency Medical Services System Act of 1973 mandated the development of an organized pre-hospital and hospital system for caring for traumatized and/or burned patients, and the concept of designating certain hospitals as area or regional centers for trauma care resulted.

In North Carolina in the mid-1970s, there were few data on which to base decisions as to how many trauma centers were necessary, where they should be located, and what level of capability they should possess. The North Carolina Committee on Trauma of the American College of Surgeons recommended that the North Carolina Office of Emergency Medical Services develop methods of collecting data that described the number of traumatized and/or burned patients each year in North Carolina, how severely injured they were, when the event occurred, where in the State it occurred, and the cause. A steering committee was formed which obtained funding for a study by the De-

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partment of Epidemiology, the University of North Carolina School of Public Health.

The objectives of the study were:

- To quantitate the number of severe trauma and burn patients in the State of North Carolina;
- To determine the location of accidents that cause trauma and burns (home, recreational area, work place, highway, etc.);
- 3) To identify transfers to a referral hospital;
- 4) To identify the outcome at discharge or at 30 days following the accident, whichever came first.

#### Methods

A retrospective study was undertaken of the charts of patients with trauma and/or burns admitted to 24 hospitals between June 1 and November 30, 1982. Three Level I statewide trauma centers had already been designated since they met the guidelines promulgated by the American College of Surgeons as modified by the North Carolina Office of Emergency Medical Services. Using these same guidelines, nine hospitals felt by the investigators to have the potential for Level II designation were also included.

Additionally, a random stratified sample of the 107 hospitals with the potential to be designated Level II-III (the larger community hospitals) and III (the more typical small

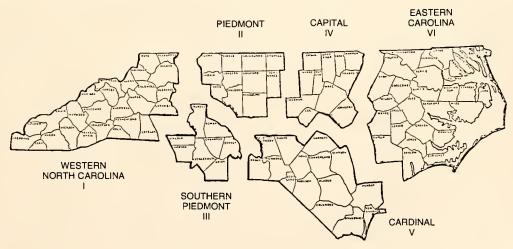


Figure 1. North Carolina Health Service Areas

community hospital) was prepared. These hospitals had an Emergency Department with 24 hour physician coverage. Twelve hospitals from this sample were included in the study. The sample was stratified in that two hospitals were selected in each Health Service Area (HSA) of North Carolina (figure 1).

Events occurring on all days between June 1, 1982 and December 1, 1982 were used in the study. This period included three major holidays: the Fourth of July, Labor Day and Thanksgiving Day.

Sixteen nurses recruited from the statewide membership list of the Emergency Department Nurses' Association were hired to collect data. They were selected on the basis of living near or working in the major hospital in the HSA. Five of the sixteen nurses left the study before the data were complete; no data from these five are in the final

Table 1 Trauma Score Determination Parameter Severity Score Glascow Coma Scale 14-15 5 (see below) 11-13 4 8-10 3 5-7 2 3-4 1 Respiratory rate 10-24/min 25-35/min 3 36/min or greater 2 1-9/min none 0 Respiratory expansion normal retractive/none n Systolic blood 90 mm Hg or greater pressure 70-89 mm Hg 3 50-69 mm Hg 2 0-49 mm Hg no pulse 0 Capillary refill normal 2 delayed none 0 Total Trauma Score 1-16 Glascow Coma Scale Eye opening response spontaneous 4 to voice 3 to pain 2 none Best verbal response oriented 5 confused inappropriate words 3 incomprehensible 2 -sounds none Best motor response abeys command 6 5 localizes pain withdraws (pain) 4 flexion (pain) 3 extension (pain) 2 попе Total (apply this score to GCS 3-15 portion of Trauma Score

above)

analytic file.

Training and re-training sessions were held in Chapel Hill at the University of North Carolina. The investigators participated in each of the sessions, giving the introduction, the research design, a summary of the monitoring system and quality control procedures. The biostatisticians usually described the formation of the analytic file; the statistical aide reviewed the questionnaires. Each nurse attended at least two sessions, one training and one retraining session.

Patient records were eligible for the study if the patient entered the Emergency Department with a diagnosis of trauma and/or burn in the Department's chronological log. Other eligibility criteria were:

 Trauma scores of 15 or less (see table 1) with the following exceptions:

(a) All hospitalized skull fractures, even if the trauma score was 16 (included head trauma held in Emergency Department 24 hours or longer);

(b) All second and third degree burns involving more than 20% of the body, even if the Trauma Score was 16:

(c) Amputations, paraplegics, and quadriplegics regardless of trauma score;

Snake bites were included if the trauma score was 15 or less.

Patients said to be dead on arrival were excluded from the study because they did not use the health facility.

In those cases in which the International Classification of Disease (ICD 9th edition) code was not available on the chart, the statistical aide assigned codes based on the written diagnoses in rank order. The aide and the principal investigator coded 62 records in this manner. As part of the quality control, these 62 records were given to a nosologist from a major medical research center for approval

Diagnostic		Prin diagr	nary nosis
group	ICDA	#	(%)
Fractures	800-829	575	( 33)
Dislocations	830-839	5	(0.3)
Sprains	840-848	4	(0.2)
Intracranial injury	850-854	413	(24)
Internal injury (trunk)	860-869	281	(16)
Open wound of head/trunk	870-879	139	(8)
Open wound of upper limb	880-887	29	(2)
Open wound of lower limb	890-897	29	(2)
Injury to blood vessels	900-904	20	( 1)
Superficial injury	910-919	3	(0.2)
Contusion (with intact skin)	920-924	11	(0.6)
Crushing injury	925-929	8	(0.5)
Foreign body	930-939	2	(0.1)
Burns	940-949	98	( 6)
Injury to nerves and spinal cord	950-957	18	( 1)
Traumatic complication/injury	958-959	35	(2)

Other

Total

1703 (100)

2)

33

990-995

Table 3
Frequency of Causes of Injury

External cause		Frequency	%
Railway accidents	E800-E807	4	( 0.2)
Motor vehicle traffic accidents	E810-E819	808	(47)
Motor vehicle nontraffic accidents	E820-E825	45	( 3)
Other road vehicle accidents	E826-E829	27	( 2)
Water transport accidents	E830-E838	6	( 0.4)
Air and space transport accidents	E840-E845	6	(0.4)
Vehicle accidents not elsewhere classified	E846-E848	3	( 0.2)
Accidental falls	E800-E888	143	(8)
Accidents by fire and flames	E890-E899	62	(4)
Accidents due to natural factors	E900-E909	10	(0.6)
Accidents due to submersion, suffocation	E910-E915	22	( 1)
Other accidents	E916-E928	163	( 10)
Late effects of accidental injury	E929	0	(0.0)
Suicide and self-inflicted injury	E950-E959	45	( 3)
Homicide and injury by other	E960-E969	228	( 13)
Injury, undetermined if accident	E980-E989	125	( 7)
War injury	E990-E999	0	(0.0)
Total		1697	(100)

or correction of the codes.

From the initial 62 forms, a list was started of the descriptions written in by the field staff, with the appropriate ICD code suggested by the hospital nosologist; this list was used for 93 succeeding records that did not contain codes but contained written descriptions of the diagnoses. Any new descriptions requiring codes were approved by the hospital nosologist before being entered into the analytic file.

#### Results

A total of 1,703 trauma events, 114 of which involved burns, were studied. Women were represented in 26% of the events and men in 74%. Of the 1,703 events, 41.8% had a Trauma Score of 12 or less; in contrast, 17.5% of burns had a Trauma Score of 12 or less.

Major diagnoses are given in table 2, and the causes of injury are listed in table 3. The leading causes were motor vehicle accidents (47%), homicide (13%), other accidents (10%), accidental falls (8%), injury, undetermined if accident (7%), accidents by fire and flame (4%), suicide

Table 4
Trauma Cases by HSA and Hospital Level

	Le	vel of hosp			
HSA	İ	II .	111*	Total	(%)
1		53	55	108	( 6
2	257	189	31	477	( 28
3	-	243	28	271	( 16
4	184	179	31	194	( 23
5	_	283	74	357	( 21
6	_	59	37	96	( 6
NC	441	1006	256	1703	(100)
	(26%)	(59%)	(15%)		(

\*Includes Levels II-III and III.

(3%), motor vehicle non-traffic accidents (3%) and all other causes (5%) (table 3).

Table 4 shows the distribution of the events by HSA and level of hospital. If a patient entered a Level III hospital in the study and was later transferred to a Level 1 hospital (both had to have been in the study, by design), the patient is represented in this study twice.

The frequency distribution of the trauma scores for all events is given in table 5. Since we specified by design that we were interested in severe trauma, with a score of 15 or less, only 11% of the events discussed here had trauma scores of 16, and these represent the exceptions

Table 5
Frequency of Trauma Scores Sampled

T	۱۵	Level of hospital				
Trauma score	1	II	III*	Total	(%)	
16	62	102	29	193	( 11)	
15	64	188	33	285	(17)	
14	78	174	46	398	(18)	
13	52	136	26	214	(13)	
12	41	102	26	169	(10)	
11	24	64	17	105	( 6)	
10	18	46	8	72	(4)	
9	17	32	7	56	(3)	
8	22	33	7	62	(4)	
7	17	15	8	40	( 2)	
6	10	23	1	34	( 2)	
5	4	13	3	20	( 1)	
4	4	10	4	18	( 1)	
3	8	7	2	17	( 1)	
2	9	5	3	17	( 1)	
1	10	56	36	102	(6)	
Total	440	1006	256	1702	(100)	
	(26%)	(59%)	(15%)			

\*Includes Levels II-III and III.

NOTE: One case has missing trauma score

Table 6
Cases of Trauma Sampled by Age and Severity of Trauma

	Age								
	0-4	5-14	15-24	25-34	35-49	50-64	65+	Total	%
Moderately									
<b>Se</b> vere (≥13)	62	121	258	204	141	107	87	980	( 59)
Very Severe									
(≤12)	41	64	218	159	111	54	41	688	(41)
Total	103	185	476	363	252	161	128	1668	(100)
	(6%)	(11%)	(28%)	(22%)	(15%)	(10%)	(8%)	1000	(100)

Table 7
Estimated Number of Trauma Cases in North Carolina

	Lev	el of hos			
HSA	T	П	1111*	Total	(%)
1	_	106	1462	1968	( 22)
II	514	378	477	1369	( 19)
Ш	_	486	484	970	( 14)
IV	368	358	362	1088	( 15)
V	_	566	900	1466	( 20)
VI	_	118	567	685	( 10)
NC	882	2012	4252	7146	(100)
	(12%)	(28%)	(60%)		, ,

\*Includes Levels II-III and III

noted earlier regarding burns, skull fractures, amputations, paraplegics, and quadriplegics. Forty-one percent of the patients had a trauma score of 12 or less; nearly half of these occur between 12 and 10, with a small peak at the low end with a score of one.

In table 6 trauma events are described by severity and age of the patient. The most obvious factor seen when events are stratified this way is the frequent occurrence of trauma in the 15-24 year age group. This age group is almost equally represented among those with trauma scores equal to or >13 (moderately severe), N=258, and those with trauma scores equal to or <12, N=218. This contrasts with the entire group in which 59% of the events were moderately severe and 41% were very severe.

When burns are separated from the overall results, it becomes apparent that burns are managed differently from all other trauma. Nearly half (48%) of the 114 burns were treated in Level I hospitals, 38% in Level II hospitals and 14% in Level II-III hospitals. Burn patients apparently are more often transferred to Level 1 hospitals. This assumption is made since 46% of the burns sampled were treated in HSA 1V, in which two of the Level I statewide trauma centers are located, one having a burn unit and one a burn center (by American Burn Association definition). The frequency of distribution of burns was noted to be entirely different from other trauma: 41% had a trauma score of 16, a trauma score of 12-2 occurred very infrequently and 4% had a trauma score of 1. Burns were documented in all age groups in approximately the same proportion. The total of 114 burn events may well under-represent burns, since the study did not include the major cold season in North Carolina.

Men comprised 76% of all trauma/burn events and women 24%. This trend continues in burns alone where 30% of the events occurred in women, 70% in men. Thirty-two percent of burns occurred in blacks as opposed to 20% of all trauma.

Since a random sample of hospitals was studied, it is of great interest to expand from this study to the entire state. An estimated 7,146 severe trauma events occur in North Carolina annually, based on the number of emergency department visits reported in 1980. Although the estimate for the entire state is considered to be quite accurate, estimates for each HSA cannot be precise. This is in large measure due to the fact that rather small numbers are being multiplied by a factor of 200. The statewide distribution of severe trauma by HSA is shown in table 7. Somewhat interesting is the large amount of severe trauma estimated to occur in HSA V (20%), especially when com-

Table 8
Motor Vehicle Accidents — Persons Injured and Persons Killed, by HSA

HSA	Persons Injured	Percent	Persons killed	Percent
1	12,329	14.7	230	17.4
H	16,830	20.1	194	14.7
III	16,997	20.3	183	13.9
IV	11,451	13.6	179	13.6
V	12,538	15.0	244	18.5
VI	13,706	16.3	288	21.9
TOTAL	83,851	100.0	1,318	100.0

Table 9
Estimated Number of Burn Cases in North Carolina

Level of hospital							
HSA	1	П	m*	Total	(%)		
1		4	80	84	(19)		
II	34	4	31	69	(15)		
Ш		20	35	55	(12)		
IV	76	18	58	152	(34)		
V	_	38	36	74	(17)		
VI	_	2	15	17	(4)		
	110	86	255	451	(10)		
	(24%)	(19%)	(57%)				

'includes Levels II-III and III.

pared with that of HSA V1 (10%). These two areas of the state are generally viewed as very similar in terms of geography, population, and socioeconomic characteristics. To attempt to verify the distribution of severe trauma, the number of persons injured and killed in motor vehicle accidents by HSA was evaluated. Since motor vehicle accidents are the cause of 51% of all severe trauma, this was seen as the best available indicator for this purpose. This distribution is shown in table 8. With one major exception, the distribution of traffic fatalities by HSA generally confirms that of severe trauma found in the study. For instance, HSA V, which had 20% of the severe trauma, had 18.5% of the motor vehicle deaths. The one significant exception to this correlation is in HSA VI which was found to have 10% of the severe trauma, but 21.9% of the motor vehicle fatalities. This could be an indication that the study underreports severe trauma for HSA VI. However, it could also logically be interpreted to reflect that a larger amount

Table 10
Estimated Number of Trauma Cases in North Carolina by Severity

Trauma	Lev	el of hos			
score	1	II	111*	Total	(%)
16	124	204	456	784	( 11
15	128	376	510	1014	( 14
14	156	348	742	1246	( 17
13	104	272	505	881	( 12
12	82	204	425	711	( 10
11	48	128	298	474	( 7
10	36	92	147	275	( 4
9	34	64	121	219	( 3
8	44	66	94	204	( 3
7	34	30	122	186	( 3
6	20	46	27	93	( 1
5	8	26	54	88	( 1
4	8	20	55	83	( 1
3	16	14	28	58	(0.8
2	18	10	54	82	( 1
1	20	112	615	747	( 11
Total	880	2012	4252	7146	(100
	(12%)	(28%)	(60%)	_	,

\*Includes Level II-III and III.
NOTE: Totals may not add due to rounding.

Table 11
Estimated Number of Burn Cases In North Carolina by Severity

Trauma	Lev	Level of hospital			
score	1	П	111*	Total	(%)
16	52	26	124	202	( 45
15	20	14	12	46	( 10
14	18	18	38	74	(16
13	8	8	27	43	(10
12	2	4	12	18	( 4
11	0	4	0	4	( 1
10	0	2	0	2	(0.4
9	0	0	0	0	(0.0
8	2	2	15	19	( 4
7	2	0	0	2	(0.4
6	4	2	0	6	( 1
5	0	0	0	0	(0.0
4	2	0	0	2	(0.4
3	0	0	0	0	(0.0
2	0	0	0	0	(0.0
1	0	6	27	33	( 7
Total	110	86	255	451	(100
	(24%)	(19%)	(57%)		

\*Includes Levels II-III and III.

of the severe trauma in HSA VI is due to motor vehicle accidents than in the other HSAs. Most motor vehicle deaths occur on rural two lane roads, which are prevalent in that part of the state. Another factor is that there is only one major population center in the HSA; thus, the nonhighway trauma such as gunshot wounds, stabbings and other violent acts are proportionally less in HSA VI. Comparing the motor vehicle fatality figures with the severe trauma figures indicates that there is a higher mortality rate in HSA V1 from severe trauma than in the other HSAs. The classification of persons injured in motor vehicle accidents includes a wide range of injuries from the very minor to the severe, the latter being the focal point of the Trauma Incident Study. Thus, these figures need to be viewed with caution especially when comparing them with the data from the study.

Of the total projected trauma patient load, an estimated 15% (1,072) are projected to require transfer, 179 to Level III hospitals, 286 to Level II hospitals and 607 to Level I hospitals.

Table 9 projects the number of burns in the entire state for a period of one year. This projection was made in a fashion similar to that used for severe trauma, and assumes that the incidence of severe burns is not seasonal, that is, that burns occur at approximately the same incidence during the summer and fall months as during the winter and spring months. The projection indicates that approximately 451 severe burns occurred for the entire state in the year 1982.

Tables 10 and 11 indicate the burden of trauma and burns by severity score. Again, a bi-modal distribution is seen, with the majority of patients falling above a trauma score of 12 and with a second peak at a score of one. The preponderance of burns have high trauma scores when initially seen (>12).

Expanding the data to an estimate for the statewide

Table 12
Percent Mortality by Trauma Score and Hospital Level

Trauma	Le	Level of hospital				
score	1	11	iii	Total		
16	10	0	3	4		
15	8	1	6	3		
14	10	3	7	6		
13	12	6	0	7		
12	10	12	8	11		
11	21	11	6	12		
10	6	22	0	15		
9	35	34	14	32		
8	36	42	0	35		
7	53	60	38	53		
6	70	61	0	62		
5	100	69	67	75		
4	100	70	75	78		
3	88	86	50	82		
2	100	80	67	88		
1	100	89	100	94		
Total	23	17	22	19		

yearly incidence did not change the etiology with fractures, head injuries and internal trunk injuries comprising an estimated 33%, 26% and 16%, respectively. Motor vehicle accidents are projected to account for 51% of injuries, with attempted homicide, attempted suicide and undetermined etiology accounting for an additional projected 20%. Young men, ages 15-24, continue in the projected data to account for 77% of all trauma, an estimated 5,472 cases.

#### Mortality

There were 326 deaths (19%) among the 1,703 cases of trauma and burns during the first 30 days after the event. One-third (31%) of the deaths occurred in Level I hospitals, half (52%) occurred in Level II hospitals and the remainder (17%) occurred in Level II-III community hospitals.

The percent mortality by trauma score and by level of hospital is shown in table 12. The overall mortality rises with decreasing trauma score: there is a 3 to 7% mortality in those "moderately severe" (16 through 13) and an 11 to 94% mortality in those "very severe" (12 through 1).

Of the 326 deaths that occurred, 14% had moderately severe trauma (trauma scores >12), 86% had very severe trauma (trauma scores <11). Eighteen percent of the deaths occurred in Level II-III and III hospitals, 52% in Level II hospitals and 30% in Level I hospitals. Among the moderately severe trauma cases, mortality was 5%, ranging from 4% in community hospitals to 10% in Level I hospitals. Of those with severe trauma, mortality was 39%, ranging from 38% in Level II hospitals to 40% in Level I and 42% in Level II-III and III hospitals.

#### Complications

Seven percent of complications occurred in Level II-III and III community hospitals, 26% in Level I hospitals and 67% in Level II hospitals. The overall complication rate was 10% for Level III hospitals, 24% for Level I hospitals and 27% for Level II hospitals, with an average statewide complication rate of 23%.

Table 13 Transfers among Hospitals

	Transfer rate		
	Low estimate	High estimate	
To Level III	2%	3%	
To Level II	3%	5%	
To Level I	8%	9%	
Total	13%	17%	

There were 399 complications in the 1,703 cases of burns and trauma. Complications demonstrate a different distribution than mortality: the highest proportion of complications were in those with trauma scores of 12 through 15. In the cases with low trauma scores, death was a more common outcome.

Nearly half (48%) of the 399 complications occurred in moderately severe cases and more than half (52%) in very severe cases.

The place of injury was the street or highway in 51% of the cases. The home was the site for a further 24% of trauma cases. There were 8% in which the site was unknown, and 83 cases were missing this information. Public buildings, farms, recreational, residential and other specified places were the sites in 2 to 4% of trauma cases. Industrial sites were listed in only 3% of trauma cases.

Of the 1,430 cases in which the information was available, most (64%) of the fractures occurred on the street/highway, most (67%) of the intracranial injuries occurred on the street/highway, 35% of the open wounds of head/trunk occurred in the home, and most (68%) of the burns occurred in the home. It is noteworthy that only 11% of the burns occurred in industrial sites.

Mortality is nearly 100% in patients with very low trauma scores, regardless of the level of the hospital to which they are admitted. Regardless of level, the twenty-four hospitals in this study had very similar patterns of mortality in serious trauma cases.

The transfer rate among hospitals was estimated by taking into consideration three types of transfers (table 13): (1) patients transferred from Levels I, II, and III to a Level Ill hospital, (2) patients transferred from Levels I, II, and Ill to a Level I hospital, (3) patients transferred from Levels I, II, and III to a Level II hospital. Transfer rates were calculated taking into consideration the fact that some of the patients who were transferred from one study hospital to another did not have two forms in the study. On the other hand, some patients had only one study form but the information on that form implied a transfer that should have led to two forms. This ambiguity was handled in two ways: (1) The first ignored all transfer information for those patients for whom there was ambiguous evidence about transfers. (2) The second assumed that each of the ambiguities was a genuine transfer.

Calculations using (1) and (2) reflect the low and high estimates of transfer rates, respectively, shown in table 13. These rates are 2%, 3%, and 8% for the low estimate, which total a transfer rate of 13%. High estimates of transfer rates are 3%, 5%, and 9%, which translates into a transfer rate of 17%. In either case, in table 13 we observe

Table 14
Survival Rates: Champion vs North Carolina

	Percent Survival		
Trauma score	Champion	North Carolina	
16	99	96	
15	98	97	
14	96	94	
13	93	93	
12	87	89	
11	76	88	
10	60	85	
9	42	68	
8	26	65	
7	15	47	
6	8	38	
5	4	25	
4	2	22	
3	1	18	
2	0	12	
1	0	6	

an increase in transfer rates from Level III to Level I hospitals as would be expected.

#### Discussion

Two important reasons for undertaking the present investigation were (1) to collect demographic data to allow future planning for the care of traumatized/burned patients in North Carolina and (2) to provide data concerning the present management of traumatized/burned patients in North Carolina enabling the comparison of practice in North Carolina with practice elsewhere in the nation. The trauma score as described by Howard Champion (table 1) was utilized because it represents the current most widely utilized predictor of ultimate patient outcome. Champion originally field tested the trauma score method on some 2,000 patients in the suburban Washington, D.C. area and observed a mortality of 13% associated with a trauma score of 12. He rather arbitrarily recommended that patients with scores of 12 and below be transferred to a Level I trauma center. While this system accurately described trauma care in Northern Virginia and suburban Maryland surrounding Washington, we questioned whether the system could be applied in North Carolina. As can be seen in table 14, there is general agreement between the North Carolina data and those collected by Champion, with the mortality rate for the trauma score 12 patients in North Carolina being 11% as opposed to 12% in Champion's practice. Two differences do exist in the North Carolina data. By including only patients with skull fractures who had a trauma score of 16 and eliminating all other injuries with a trauma score of 16, we had a mortality of 4% versus Champion's mortality of 1%. This difference is probably not significant and is more a reflection of the fact that we had relatively few patients compared with the number in Champion's series. It would appear that we are doing slightly better in terms of mortality for patients with trauma scores less than 12. However, all of the trauma scores gathered in North Carolina must be interpreted with caution since they were collected retrospectively, often estimated from data gleaned from the chart. We feel relatively comfortable with the

statement that we are probably not doing any worse than other nationally recognized centers for trauma care.

The fact that a large number of the patients with burns who eventually died were first seen with a trauma score of 16 is in no way an indictment of the trauma score system. Rather, it illustrates why the American Burn Association has developed a different system for predicting burn mortality based on age and percent burn, since the trauma score does not accurately predict burn outcome.

How many trauma centers and what level of capability are appropriate for North Carolina? The cost of operating a Level I trauma center has variously been estimated at between \$1 and \$3 million annually. The American College of Surgeons has estimated that at least 1,000 multiplyinjured admissions per year are necessary for a Level I center to approach cost effectiveness and for its personnel to maintain necessary skills. Much of the costs associated with trauma center operation represents fixed costs that go on whether patients are being cared for or not. Thus, a large organization such as the Maryland Institute for Emergency Medical Services, seeing 10,000 cases annually, can provide care at a lower cost per case than a center seeing fewer patients. The cut-off for a trauma score appropriate for transfer to a Level I center is an economic, political, and social decision beyond the scope of this paper, but assuming a trauma score of 12 or less as reasonable, 45.8% of the 7,146 trauma events predicted to occur annually in North Carolina would require such transfer. Using the ACS concept of a minimum of 1,000 cases per year per Level I center (a figure with which the authors agree), then the three Level I statewide trauma centers already designated in North Carolina appear to be adequate. The case for only three Level I centers becomes even stronger in light of the average survival of 2.5% among patients with a trauma score of 6 or less according to Champion. (Even if the trauma event occurs outside the door of a Level I center, an estimated 1,129 patients would have a slim chance of surviving.) The North Carolina survival data are perhaps more encouraging, but few would argue that the 11% of North Carolina cases (786) with a trauma score of 1 are, for practical purposes, unsalvage-

Other factors obviously have to be taken into consideration. The geography of North Carolina is such that the three Level I statewide centers at the time of this study, located in Durham, Chapel Hill and Winston-Salem, are too far from the far eastern and western parts of the State to be accessible for the kinds of patients appropriate for transfer. The major difference between Level I and Level II capability lies in the research and educational missions assigned to Level I. Minor differences exist in areas of inhouse availability of physicians, and the range of patient care is nearly identical. It might be argued that the geographic areas of the State not in the vicinity of one of the three current Level I centers might be covered satisfactorily by appropriately located Level II centers. Equally supportable, however, would be the designation of two additional Level I centers, one in the east (as has been done with Pitt Memorial Hospital) and one in the west, recognizing the important role that an educational outreach program has in orienting a patient catchment area toward a

given center and the general upgrading of patient care that might result.

An interesting finding of the study was the higher mortality and morbidity in Level 1 and 11 hospitals vs. Level 111. These findings are not explained by sicker patients being seen in Level 11 and 1 hospitals since the distribution of patients by trauma score was similar. Further analysis of the data to determine if, for example, patients with head injury and a trauma score of 12 or less were transferred whereas those without head injury and a trauma score of 12 or less were retained in Level 111 hospitals did not prove to be helpful. Most patients transferred were from a Level 111 to a higher level hospital. Examination of this group did not reveal a trauma score distribution or a mortality rate significantly different from the overall data.

The 17% transfer rate is slightly higher than the nationally predicted 5-10% but is partly influenced by the number of patients with burns, who are more apt to be transferred than patients with non-thermal trauma. This also represents the high estimate. An estimated 663 or only 9% of patients per year with trauma scores of 12 or less will be treated in Level III hospitals if the referral methods in use at the time of this study continue. Whatever the method of selection, in view of the mortality and morbidity figures, it appears to be functioning fairly well. This is not to say that it could not be improved upon if a different referral practice were enacted.

Levels I and II differ primarily in the research and educational missions assigned to Level I. Since the three Level I hospitals were already designated and had in-house dedicated trauma teams at the time of the study, it is

interesting to speculate that this accounts for the slightly lower morbidity and mortality for a group of patients with the same severity of injury compared with the results in Level II hospitals. It should be remembered that the "Level II" hospitals in the study reflect only the investigators' estimate that these hospitals had the potential for eventual designation as Level II by the State. Since we can anticipate the bulk of trauma care to be conducted in Level II hospitals in the future, particular attention needs to be paid to their in-house capability so that they are as close to Level I as possible, short of research and education.

Any reduction in mortality or morbidity after the trauma event pales in light of the potential for trauma and burn prevention. Sixty-eight percent of the trauma resulted from highway related accidents, homicide, and suicide. Preventive efforts need to be directed toward maintaining a reduced speed limit, enforcing required seat-belt usage, eliminating driving while impaired, and gaining some control over gun usage, particularly for the target population composed of men between 15-24 years of age. One of the safest places to be in North Carolina is at work. The majority of burns occurred in the home, predominantly at mealtime and at bedtime. Education efforts about unattended children in the kitchen, safer heating systems, and fire retardant clothing should be high target areas for burn prevention.

ACKNOWLEDGMENT: We are grateful to Dennis Gillings, Ph.D. and Caroline Becker, M.D., for their assistance in collection and analysis of these data.

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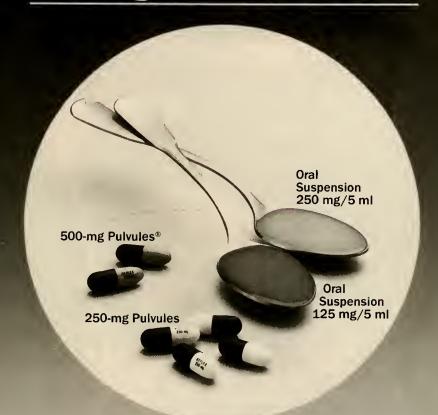
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Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment, howreported. Such elevations may disappear even with continued treatment, how-ever, four cases of hepatocellular injury by verapamil have been proven by re-challenge. Periodic monitoring of liver function is prudent during verapamil challenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W.P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rarely, discontinuation and institution of appropriate therapy depending upon the clinical situation Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortality rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including smus pradycardia, 2° AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. Precautions: ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excesmonitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and propranolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by S0% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over- or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quindine therapy in patients with hypertrophic cardiomyopathy should prob-ISOPTIN administration. Until Turtner data are obtained, complined ISOPTIN and quinding therapy in patients with hypertrophic cardiomyogathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames suggest a turning eithe potential, and verlaparin was not included in the state of the studies in pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk, therefore, nursing should be discontinued during ISOPTIN use **Adverse Reactions:** Hypotension (2.9%), peripheral edema (1.7%), AV block 3rd degree (0.8%), bradycardia HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported (See Warnings.) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, pursons a psychotic symptoms, confusion, parethesia, propries bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation How Supplied: ISOPTIN (verapamil HCI) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochloride and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLI" on the reverse Revised August, 1984



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#### Jacob

- We present two views of Jacob, a man with severe congenital ichthyosis.
   The first view is that of Douglas S. Diekema, M.D., who saw Jacob in dermatology clinic during his student years at The University of North Carolina at Chapel Hill School of Medicine. The second view is that of Claude S. Burton, M.D., who reacts to Dr. Diekema's paper.
- I. Douglas S. Diekema, M.D.: I first encountered Jacob in dermatology clinic. He was a gentleman with severe congenital ichthyosis, a genetic disorder which from birth leaves its victims covered with scale from scalp to sole. No portion of the body remains untouched, and these unfortunate people must pass through life with an outer cloak more reminiscent of a reptile's than a human being's. Their skin, presented daily to the world's critical eye, forever marks them as alien.

My first sight of Jacob left me numb. I'd never before seen a comparable tragedy — an anomaly so unlike others in appearance that he could only evoke feelings of horror and unease. A creature not unlike Victorian England's "elephant man." Yet in spite of the startling appearance, Jacob was a fellow human, a person craving affection and acceptance but shunned by society. He had become the sad and unwilling victim of the penetrating stares and flickering glares of passersby, the startled faces of protective parents, and the crass comments of those individuals who were born with more beauty but less empathy.

As we discussed his condition and the effect it had had upon his life, his sad and downward directed stare betrayed his bitterness toward a world which demanded perfection. "He's just got to learn to live with it," the dermatology attending decreed. And Jacob's eyes glistened fleetingly, a reminder of past tears shed. One can only begin to imagine the torture of this poor soul. Images flash to mind . . . a baby, too young to know the horror and anger of his frustrated parents . . . a child playing alone on the school playground, perhaps holding back a cascade of tears as his classmates gawk and squeal at this odd creature which has wandered into their near perfect world . . . a teenage high school student struggling with the same adolescent emotions and drives of those around him, but too much an outcast to play the games of youth. A world without love, full of cruelty, full of anger - a world not unlike hell which this one man must face . . . alone.

From the Calvin Center for Christian Scholarship, Calvin College, Grand Rapids, MI 49506 (Dr. Diekema) and the Dermatology Division, Duke University Medical Center, Durham 27710 (Dr. Burton).

And then came a glimmer of hope. When Jacob was twenty-five it was suggested that he be treated with an experimental retinoic acid derivative. Initially successful, the therapy erased his cursed condition entirely. Imagine the ecstasy, the pure joy of seeing his wretched figure transformed into what would certainly appear to him a near flawless figure, a virtual god, by comparison. And yet, just as Jacob came within reach of that which he desired most of this world, he was forced to watch helplessly as it was pulled forever from his grasp, for along with the attainment of a near normal appearance came the life-threatening effects of the drug's toxicity. With the drug discontinued, the scales quickly returned — his only hope dashed mercilessly in a surf from which there was no deliverance. Apparent escape had been dangled before him, and Jacob, reaching out in hope and faith, found only an empty mirage. It would be yet another card dealt against a destined loser — a lovely man dressed as a monster. And yet again, he would just have to learn to live with it.

II. Claude S. Burton, M.D.: Sooner or later virtually everyone will witness or experience human tragedy. The story of Jacob reminds me of the sorrow I have often felt for the many patients who pass through our clinics with disfiguring skin diseases. I do not believe telling a pateint that "he must learn how to live with it" is very useful. Nor do I think it is useful to tell a patient with a problem that "nothing can be done about it." I earnestly believe that no matter what the problem, there is always something that a caring human being can do and there is always something we can do as professionals to help a patient live with a problem. It matters little if the problem is dermatologic, cardiac, chronic, or even terminal. It is the nature of human beings to share our experiences, good, bad, life, and death. Why should Jacob be without hope - "his only hope dashed mercilessly in a surf from which there was no deliverance"? Hope and humanity are inseparable. No one has a right to deny hope. In this case, Jacob enjoyed complete remission, though temporary, and has every right to hope for another miraculous drug with even fewer side effects. I hope someone was there to comfort him, to share his disappointment, and to offer him hope.

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#### A Celebration of John Borden Graham, M.D.

R. John B. Graham, Alumni Distinguished Professor of Pathology, will be honored at a program in Chapel Hill at The University of North Carolina School of Medicine beginning at 9:00 a.m. on Friday, April 25, 1986. The program will consist of (1) a symposium with morning and afternoon sessions in which topics in blood coagulation and genetics will be presented by nationally recognized persons in these disciplines; (2) a luncheon at which the Coagulation Laboratory of North Carolina Memorial Hospital will be dedicated and named in honor of Dr. Graham; and (3) an evening banquet with a featured speaker and other activities including presentation of a bound volume of letters from current and former students, staff and laboratory associates, colleagues and friends.

A member of The University of North Carolina at Chapel Hill faculty since 1946, Dr. Graham has made major contributions as a scientist and a teacher. In so doing, he has brought high honor to himself and the University.

As Chairman of the Genetics Training Committee of the National Institutes of Health in the late 1960s and early 1970s, Dr. Graham helped establish the pattern of training in genetics in the country's top universities. He also served as Secretary and President of the American Society of Human Genetics. Here at home, he was a founder of the Genetics Curriculum and served as Chairman from its start in 1963 until he retired in July of 1985.

Dr. Graham's signal contributions to progress in un-

derstanding coagulation disorders include his discovery of the Stuart Factor, named for one of Dr. Graham's patients. Activation of the Stuart Factor, now known as Factor X, has proven to be the key step in blood coagulation.

Dr. Graham is Director of the Division of Research in Thrombosis and Hemostasis in the Department of Pathology, a coagulation research program which last year received a five-year renewal grant of nearly \$2 million from the National Institutes of Health.

Because of his interest in population problems, Dr. Graham exerted strong leadership in development of the UNC Population Center. He served as its Chairman from 1964 to 1967 and then as Secretary of the Center's policy board.

Dr. Graham has been a sometime contributor to the North Carolina Medical Journal, which has provided him with a forum for expressing his views on a wide range of subjects, including socialized medicine (1958), death (1964), the population explosion (1967), Dr. James Bullitt (1984), Dean Berryhill (1984), human experimentation (1984), how to be a good administrator (1984), medical school admission policies (1985), student research (1985) and faculty recruitment (1986). It would be incorrect to believe that he does not have strong views on all these subjects, and on many others which he has not yet gotten around to putting on paper.

For further information about the Graham fete, call 919/

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### Marching to a Different Cactus: Peyote (Mescaline) Intoxication

Ronald B. Mack, M.D.

It seems to me that if I had decided to "chuck" it all and seek inner peace by living alone in a log cabin for two years and then writing about it who would care? Doesn't seem like it would get me on a talk show or a best seller list. But that exactly is what Henry David Thoreau did at Walden Pond and people cared. (Do you see him on the Donahue Show?)

Thoreau was about 28 years old when he decided to leave his career as a school teacher-surveyor-handymangardener and get back to nature. He apparently was not too successful with the ladies and when his brother John died of tetanus he must have felt like he needed to get away, to sort things out. So in 1845 he built himself a log cabin near Walden Pond and spent two years there, ultimately writing Walden Pond, one of the great treasures of American literature. In this book he said so many things that have become part of the way we think and act in this country such as "the mass of men lead lives of quiet desperation. What is called resignation is confirmed desperation"; "I also have in my mind that seemingly wealthy, but most terribly impoverished class of all, who has accumulated dross, but know not how to use it, or get rid of it, and thus have forged their own golden or silver fetters." I must admit that my favorite expression from Thoreau's writings is "If a man does not keep pace with his companions, perhaps it is because he hears a different drummer. Let him step to the music which he hears, however measured or far away."

There are others who feel that becoming detached from the pressures of everyday living and acquiring an exploration of their inner being can better be achieved chemically. And what better way to do this than to take into your body a natural substance — Thoreau loved natural things. "What is the pill that keeps us well, serene, contented? For my panacea let me have a draught of undiluted morning air." One such product comes from a cactus that grows in rocky deserts and is said to be the most spectacular hallucinogenic plant in the Americas. What is its name? You guessed it — peyote. It has been used by Indian tribes for centuries and is still being used even as we speak. The peyote is sort of an ugly creation, at least it is to me; it is a small, fleshy, spineless cactus with a rounded gray-green top, tufts of white hair and a long carrot-like root. (Great Heavens Above — we have a new intern who looks like

that!!). This cactus is native to the Rio Grande valley of Texas and the northern and central parts of the Mexican Plateau.

There are probably dozens of known secondary substances found in peyote but the most important of these alkaloidal chemicals is mescaline. Peyote generally refers to the unmodified cactus. That part of the cactus that is of interest to us is known as the "mescal button" - it contains the mescaline. Typically the crowns of the cactus are cut off to sun dry into brown, disc-shaped buttons that can survive and retain hallucinogenic potency for rather long periods. Mescaline is a trimethoxy indole and resembles neurotransmitters such as dopamine and norepinephrine, i.e., is a phenethylamine alkaloid. It was first isolated from peyote at the fin de siécle (1896) and was synthesized in 1918. That's right, if you cannot find this wicked cactus in nature you can make some or buy some already made. Peyote is ingested as a dry intact button or ground into a powder or compressed into a tablet or you could make a tea or salad out of this flora. (My five-year-old grandson sat down to the dinner table the other night in his usual chair - next to me - and his grandmother asked him what kind of salad dressing he wanted. He replied in his assertive voice, "House dressing, please." Now that is a sophisticated child of the 80s!!).

We need at this time to discuss why this partially edible cactus has been delighting audiences for centuries. The mescaline in the peyote is very rapidly absorbed. Within a period of 30-60 minutes the patient experiences nausea and vomiting, often severe. This occurs regardless of the method of introduction into the body. Now wait just one darn minute!! You mean to say that this ever popular hallucinogenic plant initially makes you sick? Yep, and it gets "worser" and "worser"; other early features include dizziness, anxiety, sometimes a panic state, tachypnea, hyperpnea, hypertension, mydriasis, chills, and profound diaphoresis. Degustibus non est disputandum (in matters of taste there is no argument). Include me out! I'm not into pain; I feel that way as it is most mornings just awaiting the medical students. These clinical adversities are often accompanied by ataxia, tremors, nystagmus and muscular fasciculations.

After one or two hours or more of these less than good sensations the hallucinogenic effects begin as the evil effects wane. This psychic or sensory phase, as it is often referred to, encompasses a feeling of well being, ecstatic euphoria, a great sense of physical power and vivid fan-

From the Department of Pediatrics, Bowman Gray School of Medicine of Wake Forest University, Winston-Salem 27103.

tasies. Apparently the effects of peyote on the mind and body are so fantastic (literally) and extraterrestrial that you begin to understand the belief of the more primitive natives of our hemisphere that the cactus contains the forces of spirits or gods and may the Force be with you. All sensory perceptions are distorted, especially visual perceptions. with intense, rich, kaleidoscopic visions with vivid colors and geometric patterns. Pseudohallucinations involving other sensory organs can also occur - smell, taste, hearing. As with LSD, synesthesia frequently occurs such that there can be a blending together of one sensory modality with another, i.e., music can be "seen" and sounds can be "felt." The user experiences the sensation of weightlessness, and time and space seem distorted. There is an overall feeling of detachment from the world as we know it with a prolonged exploration of the inner being and even, for some, mystical revelations. (I know you won't believe me but cannoli with a cup of expresso while listening to Puccini does the same thing for me — I swear it.)

It requires a dose of 5 mg/kg of mescaline to produce such a psychedelic event and each peyote button contains about 45 mg of mescaline. Thus several buttons, three up to a dozen, are needed to do the job. The "high" associated with use of this drug may last for hours and then the user usually falls asleep. This entire "trip," without leaving the house, from the early, acute, disagreeable features through the "high" sequence can last from eight to twelve or more hours. Another peculiarity of this unusual experience relates to the fact that although the user is undergoing rather weird perceptive experiences, he/she remains awake and fairly lucid even though unable to express him/herself.

If you don't live in the Southwest or Mexico you can

still purchase these "goodies" on the street - they are being made synthetically. As with most street drugs, however, you are never really sure of what you're getting. Caveat emptor, "fur sure"!! For example, pure mescaline is not usually available on the street and if you ask for it you are liable to receive LSD, PCP, "speed," aspirin, strychnine, Spam? (ick!!) There is a legal method for using peyote; yep, there really is. Peyote can be used legally in the United States by Indians who belong to the Native American Church; it is part of their religious ceremonies and church members are exempt from certain portions of the Controlled Substances Act. Fortunately for the user death from this cactus derivative is quite uncommon. Doses ranging from 20 to 60 mg/kg or more have been known to cause respiratory depression, bradycardia and hypotension. Also, for those of you who think you might want to try this stuff, remember that tolerance to mescaline develops rapidly but physical dependence does not occur.

What is the treatment if such a patient on peyote-mescaline ends up in your office or emergency room? Except for the adverse physical effects noted some users exhibit paranoid feelings, anxiety, suicidal thoughts or a desire to dress like Prince or Madonna. The treatment is mainly supportive and non-threatening. Resist the temptation to administer phenothiazines which may cause an adverse reaction if the drug was adulterated and misrepresented. Some authorities suggest the use of diazepam if the patient freaks out (and does not have respiratory depression).

Thoreau died from tuberculosis, a disease suffered by many great authors — Whitman, Emerson, Thomas Wolfe, Robert Louis Stevenson, etc. Frankly going off to the woods for more than a week would do me in. For what is a world without re-runs of "Charlie's Angels"?

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### The Plasma Sodium Concentration: What Does It *Really* Mean?"

William B. Blythe, M.D.

"When I use a word," Humpty Dumpty said, in rather a scornful tone,

"it means just what I choose it to mean — neither more nor less."

"The question is," said Alice, "whether you can make words mean so many different things."

"The question is," said Humpty Dumpty, "which is to be master—that's all."

Through The Looking Glass by Lewis Carroll

S PLENDID technological advances of the past decade or so have made almost all laboratory tests — and their results — easily and quickly available to the physician.

As a consequence of this ready accessibility and other factors, too, most laboratory tests are performed much more than they are needed and used, and, like Humpty Dumpty's words, they take on many different meanings.

The question is whether the physician, through knowledge, or the laboratory test, by virtue of a mystical quality bestowed upon it by the physician, is to be master.

There is perhaps no better case in point than the plasma sodium concentration. I know, from personal experience garnered over a quarter of a century, that a low plasma sodium concentration, hyponatremia, is equated by the unknowing variously with "sodium depletion," "dehydration," "overhydration," "water intoxication" and on and on, and that hypernatremia is equated with "dehydration,"

All these notions are decidedly incorrect!

To know the plasma sodium concentration is to know only what the relationship between sodium and water is in the plasma, whether the relationship is normal or abnormal and, if abnormal, in which direction the relationship is disturbed; that is, whether there are higher than normal amounts of sodium in the plasma in relationship to water or lower than normal amounts.

That is all it means — nothing more or less!

Clearly, this is not to say that knowledge of the plasma sodium concentration is useless information but rather that it is of no help diagnostically or therapeutically unless one is clearly aware of the clinical context in which it occurs.

Hyponatremia, for example, may result from factors, such as overzealous diuretic use, which produce a deficit of total body water as well as a *larger* deficit of total body sodium; or it may result from an excess of total body water alone such as is seen in the syndrome of inappropriate

secretion of antidiuretic hormone; or it occurs in situations in which there is an increase in total body sodium and total body water, with the excess of water being greater than the excess of sodium, such as can be seen in severe congestive heart failure.

Two other examples of hyponatremia should be mentioned. One is that which occurs in situations where the amount of water per unit of plasma is reduced such as marked hyperlipidemia or hyperproteinemia. Since sodium salts are water soluble, the concentration of sodium in the plasma water is normal, but since the amount of water per unit of plasma is reduced, hyponatremia is apparent rather than real. There is no disturbance in either total body sodium or total body water.

The other is hyponatremia that is a consequence of severe hyperglycemia. In this situation, the plasma osmolality is increased by the increased glucose level, and water moves from the intracellular compartment to the extracellular one. The plasma sodium concentration is thereby decreased.

The administration of hypertonic saline in either circumstance is not indicated and may be dangerous.

Hypernatremia is most often the consequence of reduced total body water; however, the reduction may be produced by either loss of water in excess of sodium as, for example, is seen in diabetes insipidus or by lack of intake of water. In infants or non-communicating adults, the administration of sodium salts may produce hypernatremia.

The point is that the plasma sodium concentration *per se* is of *no* value in determining the status of total body sodium or total body water and is therefore of no help in and of itself in making either diagnostic or therapeutic judgments.

The path to correct diagnosis and treatment leads, as it always does, to the bedside and a good history and physical examination, *and* to the library where an understanding of pathophysiology and the natural history of disease can be obtained.

The physician, when thereby enabled, has a good and faithful servant in the plasma sodium concentration.

From the Division of Nephrology, the University of North Carolina, Chapel Hill 27514.

### A defense against cancer can be cooked up in your kitchen.

grain cereals such as oatmeal, bran

and wheat may help lower the risk of colorectal cancer. Foods high in fats, salt- or nitrite-cured foods like ham, and

Fruits, vegetables, and whole-

There is evidence that diet and cancer are related. Some foods may promote cancer, while others may protect you from it.

Foods related to lowering the risk of cancer of the larynx and esophagus all have high amounts of carotene, a form of Vitamin A which is in cantaloupes, peaches, broccoli, spinach, all dark green leafy vegetables, sweet potatoes, carrots, pumpkin, winter squash and tomatoes. citrus fruits and brussels sprouts.

> Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

fish and

types of sausages smoked by traditional methods should be eaten in moderation.

> Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat. Weight reduction may lower cancer risk. Our 12- year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

No one faces cancer alone.

#### **EDITORIAL**

#### Happy?

John R. Gamble, Jr., M.D.

MANY of us were surprised to find out in 1984 that physicians are part of an emerging "information society" which represents more than 65% of the job positions in America. In 1950 information jobs represented only 17%. John Naisbitt told us in his *Megatrends*<sup>1</sup> that most all professionals are in information jobs — lawyers, teachers, engineers, computer programmers, system analysts, doctors, architects, accountants, librarians, brokers, reporters, social workers, clergy, nurses, bankers, and on and on.

In 1985 Mr. Naisbitt and co-author Patricia Aburdene wrote a new book entitled *Re-inventing the Corporation*<sup>2</sup> which has a special message for physicians. They assert that the big thing for the future is that work should be fulfilling and fun — otherwise this human capital (brain power) is not likely to be productive. Furthermore, this shift from capital and equipment represents jobs that are not easily controlled, so happiness in the job becomes important. Certainly no one will argue with that.

As we look into the future we see DRGs, peer review, litigation, HMOs, PPOs, physician corporate structuring, sub-specialization, hospital or industrial employment, and fixed fees. Many are saying that the fun is already gone.

The gloom and irritation that pervades many staff meetings addresses this.

Perhaps a statewide or several regional PPOs or HMOs will help, but not without leadership that will say "no" to elected officials, entrepreneurs, and social planners. If we continue to retreat under fire and release management of the health care delivery system, then we also lose our autonomy and cease to be professionals answerable only to our clients. I continue to be amazed that the medical profession has allowed this to be done to them with so little meaningful resistance.

Unfortunately many physicians think professionals are the "good guys" and gentlemen who don't argue, threaten, coerce, intimidate, or strike. We are probably looking at the last opportunity we will have to use our positions and our resources. You don't see the lawyers, bankers, or insurance companies being threatened with nationalization or socialization.

I suppose each of us assumed someone else was watching the store.

Yes, job fun and fulfillment were what we were talking about, so let's get back to a top priority.

#### References

- 1. Naisbitt J Megatrends. New York, NY: Warner Books Inc., 1984.
- Naisbitt J. Aburdene P. Re-inventing the corporation. New York, NY: Warner Books Inc., 1985.

From Box 250, Lincolnton 28092.

### OFFICIAL CALL HOUSE OF DELEGATES

# HOUSE OF DELEGATES Meetings Scheduled

Notice to: Delegates, Alternate Delegates, Officials of the North Carolina Medical Society, and Presidents and Secretaries of county medical societies.

Sessions of the HOUSE OF DELEGATES will convene in the Blue Ridge Ballroom, Grove Park Inn, Asheville, North Carolina, at the following times:

Thursday, May 1, 1986 — 9:30 a.m. — Opening Session Saturday, May 3, 1986 — 2:00 p.m. — Second Session

A member of the CREDENTIALS COMMITTEE will be present at the Desk in the Hotel Lobby, Wednesday, April 30, 1986, 3:00 p.m. to 5:00 p.m., and Thursday, May 1, 1986, 8:30 a.m. to 10:00 a.m. to certify Delegates. Delegates are urged to bring their Credential Cards for presentation at the Registration Desk. Delegate Badges must be worn to be seated in the HOUSE OF DELEGATES.

### REFERENCE COMMITTEE HEARINGS

Reference Committee hearings are scheduled to begin Thursday, May 1, 1986, at 2:00 p.m.

KENNETH E. COSGROVE, M.D., President HENRY J. CARR, M.D., Speaker JOHN T. DEES, M.D., Secretary GEORGE E. MOORE, Executive Director

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#### MODERN MEDICINE

#### Recruiting of Faculty

John B. Graham, M.D.

• A different kettle of fish.

Thave been involved off and on during the past 30 years with the recruitment of faculty members at many levels in various parts of our university, especially in the medical school. What I have learned about academic recruiting is probably transferrable to recruiting for the types of organizations that are evolving to manage health care. Now that I am in the twilight of my career, I think it is time I passed on my conclusions and recommendations about recruitment to the next generation.

Recruiting faculty members has been analogous to fishing. The process at the entry level (Assistant Professors) is reminiscent of netting small fish, while the search for a Distinguished Professor is more like fishing for swordfish in the Gulf Stream, or perhaps an oceanographic voyage.

Current "affirmative action" rules require that all faculty positions be advertised. This has opened the selection process to recent graduates of both sexes, all races, and with degrees from all sorts of institutions. Recruiting is simplicity itself at the entry level. Using the fishing analogy, it consists of placing a gill net (the advertisement) across the stream in which candidates swim (Nature, Science, The New England Journal of Medicine, etc). The net is pulled in for inspection after a suitable interval, and the choice specimens are set aside for more detailed examination. Then a small number of "short listed" candidates are vetted by a procedure similar to the one used by the pre-war Indian Army to screen the British graduates of Sandhurst, their West Point.\*

Recruiting "Stars" is entirely different. Stars do not reply to ads. They are identified by the recognition already accorded them. With certain exceptions (see below), they are satisfied with their current positions, and the challenge to the recruiter is to create the illusion that the new situation will be better than the old one. As in big game fishing, the process falls into five clearly defined stages. (For simplicity the recruitee will be referred to hereafter as the "fish.") These stages are:

- 1. Attracting the attention of the "fish."
- 2. Getting the "fish" to take the bait.

- 3. Setting the hook.
- 4. Reeling in the "fish."
- 5. Boating the "fish."

It should be emphasized that this is a very complex operation and that failure can occur at any stage. For instance, it might not be possible to attract the attention of the "fish." This is what would probably happen if one of our community colleges attempted to recruit a professor from Harvard. If the "fish's" attention can be gained, however, the challenge becomes how to get him to take the bait. There are numerous classical and time-tested ploys: pretending to need on-site "advice" (well paid, of course), an invitation to give a series of important lectures, residence for a semester or a summer session at several times the usual rate of pay, etc. Experienced recruiters always stage such events at the time of year when local weather is optimal. Recruiters who are less than completely honest will also just happen "by chance" to have at hand a newspaper account of excellent weather during whatever season the "fish" suspects is disagreeable. Such a Machiavellian recruiter will probably also have information available about the cost of housing, data that were collected when costs were at a recent minimum.†

Stars usually enjoy attention and want to be loved, so it is essential to carefully "stroke" them at appropriate intervals. Each "fish" has a different need for attention, and the recruiter must decide by instinct very early whether to be a frugal or prodigal stroker. It is more subtle and dignified to stroke by indirection and to do so at a lower rate and intensity over a longer period, but many Stars seem to have an inexhaustible need for adulation and are not repelled by constant stroking.

Once the bait has been taken, the hook must be set very carefully. To try to set it suddenly or prematurely may scare off the "fish." On the other hand, to wait too long may cause him to misunderstand the nature of the game, and he may spit out the bait. Timing is of the essence, and it is at the stage of hook-setting that the inexperienced recruiter is most apt to make a mistake.

Once it is clear that the hook has been set, reeling-in can begin. It is important to make the "fish" believe that

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<sup>\*</sup> John Masters has described this process in his autobiography, Bugles and a Tiger. When he applied to a Gurkha regiment of the Indian Army in the 1930s, he was put through a week-long scrutiny which consisted of interviews with every Tom, Dick, and Harry and getting him drunk each night, the regiment's theory being in vino veritas.

<sup>†</sup> In California, where housing costs are astronomical, many universities have full-time administrators who specialize in explaining to prospective faculty members how to arrange a mortgage to obtain the maximum tax advantage. It has been suggested that snake oil salesmen are in a sellers' market there for these positions.

swimming toward the recruiter's boat is an entirely natural and volitional act. He should be reeled in very slowly, slack being carefully taken up as it appears, but overt force should never be used.

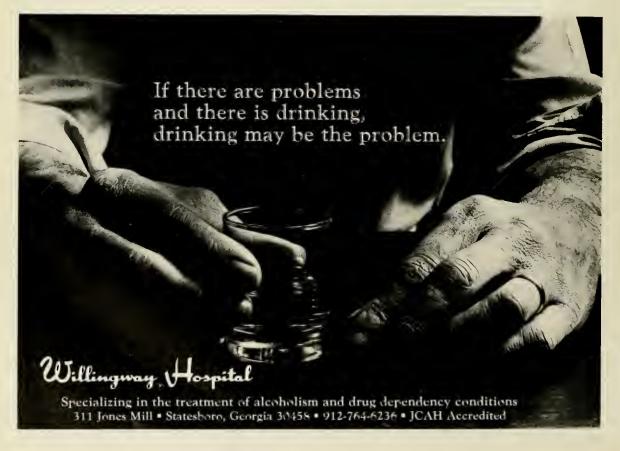
When the "fish" is alongside the boat, he must be gaffed straightaway. This is to assure that he will not break away at the last moment. The best gaffing procedure is to lay on a press conference, preferably on TV for local consumption, and to make a widely publicized announcement. Best results are obtained when the announcements are published in the *New York Times*. Most "fish" find it impossible to change their minds after these events have taken place, because to do so might suggest to their peers that they are indecisive. Recruiters are aware, of course, that indecisiveness due to compulsiveness is an academic hallmark.

It was mentioned earlier that there are exceptions to the rule that Stars are satisfied with their present situations. One can sometimes learn about dissatisfaction through the academic grapevine, and there are certain high probability situations. A Star who had hoped to become President of his institution but has been passed over is often susceptible to an outside offer. It shows his former colleagues that they have overlooked a winner and that he is still an academic figure to be reckoned with. Another high probability revolves around the break-up of a marriage. The pain accompanying divorce can be ameliorated, sometimes considerably, by several thousand miles of distance. An-

other favorable situation frequently encountered by universities in the Sun Belt is the discovery of a distinguished middle-aged professor in a Northeastern or Middle Western university who is tired of shoveling snow. (The example of the professor of similar age in the Sun Belt who longs for severe and protracted winters has not yet surfaced among the case studies of the *American Journal of Recruiting*.)

The last of the major situations for easy recruitment of Stars concerns the Star on the wane. The Star who can no longer compete at the "cutting edge" of his specialty is sometimes willing to leave a more prestigious institution for a highly visible position at a less prestigious one. He thereby assures himself of adulation up to, even beyond, retirement. The recruiter emphasizes to him the advantages of sitting in the President's box at football games and appearing regularly on the platform at convocations.

These are the main principles involved in recruiting professors. What remains is a warning. The bad news is that there is no guarantee of success. The most brilliant prospect may burn out early, or prove to be an insufferable bastard, or may be a psychological basket case. The good news is that sometimes a recruit about whom the committee had been ambivalent becomes a Star! Admittedly this is very rare, but the committee members never forget it. They talk about it for years at cocktail parties and never allow their peers to forget how prescient they were.



## Distribution of Nurse Practitioners and Physician Assistants: Are They Meeting the Need for Primary Care?

Mary Anne Salmon, Ph.D., and Jane Stein

 Although the numbers of nurse practitioners and physician assistants improves the statewide ratio of primary care providers to population, their distribution throughout the state does little to improve the lot of most underserved areas.

WHEN programs to train nurse practitioners and physician assistants began in the mid-1960s, their stated purpose was to improve access to primary care for people in underserved areas by increasing the complement of primary care providers. North Carolina has a scarcity of primary care physicians, relative to the United states as a whole, and a growing supply of nurse practitioners and physician assistants. Are these health professionals practicing in areas with shortages of primary care?

This question can be answered by using Health Manpower data4 from the licensure of nurse practitioners, physician assistants and primary care physicians.5 The most disadvantaged quarter of North Carolina in terms of access to primary care consists of the 25 counties with the highest ratios of population to primary care physicians: Perquimans, Camden, Greene, Caswell, Pender, Gates, Hoke, Bertie, Currituck, Tyrrell, Onslow, Bladen, Stokes, Franklin, Pamlico, Cumberland, Randolph, Person, Warren, Anson, Jones, Northampton, Davie, Edgecombe and Richmond. These counties, located primarily in the eastern part of the state and along the Virginia border, have from 3,100 to 9,800 people for every primary care physician practicing in the county. (The mean for the 25 counties is 4,184, which is 2.6 times the ratio of population to primary care physicians in North Carolina as a whole.) These are the counties that could reasonably be expected to benefit from nurse practitioners and physician assistants; yet, of the 890 mid level practitioners in North Carolina in 1983

— 423 nurse practitioners and 467 physician assistants—only 82 were working in the counties with primary care shortages. Almost a third of these counties had no nurse practitioners or physician assistants, and most of the remainder had six or fewer. The one exception was Cumberland county which ranked eighty-fifth in the state in its supply of primary care physicians and employed 23 nurse practitioners and physician assistants. However Cumberland county is a special case. Because it is the location of a large military base whose residents are served by federal physicians, the ratio of population to active, nonfederal, primary care physicians is a poor measure of actual care available.

Although the number of nurse practitioners and physician assistants in the most disadvantaged quarter of North Carolina is small, a larger number of these health professionals (9.2%) than of primary care physicians (7.1%) serve these areas. Furthermore, because of the practice of nurse practitioners and physician assistants, six counties that ranked in the 25 highest ratios of population to primary care physicians (thus, the poorest primary care physician supply) ranked in the second quarter in the ratio of population to primary care provider. Two of these (Northampton and Richmond counties) had only small differences in ranking which happened to fall in different quarters, but for four of them the addition of nurse practitioners and physician assistants made a substantial difference in the supply of primary care. Caswell county had a population to physician ratio of 5,276 (4th largest) but a population to provider ratio of only 2,110 (33rd largest). Similarly, Davie county had a population to physician ratio of 3,230 (23rd) and a population to provider ratio of 1,988 (37th). For Greene county those two ratios were 5,511 (3rd) and 2,362 (26th), respectively, while for Warren county they were 3,328 (tied for 18th largest) and 2,080 (35th).

The correlation between the number of nurse practitioners and physician assistants and the population-to-primary-care-physician ratio, which can be used to indicate an undersupply of physicians, is -.323, indicating that

From the Health Services Research Center, University of North Carolina, Chapel Hill 27514.

Data included in this report were made available through the cooperation of the Health Services Research Center at UNC-Chapel Hill, the North Carolina Area Health Education Centers Program, the North Carolina State Center for Health Statistics, the North Carolina Hospital Association, and the North Carolina Board of Medical Examiners. Funds for the production of this report were provided by the Area Health Education Centers Program and the Duke Endowment.

there is a moderate tendency for nurse practitioners and physician assistants to work where primary care physicians are plentiful by North Carolina standards. However, the match between the availability of primary care physicians and the employment of midlevel practitioners is far from perfect. The 25 counties in which primary care physicians are most abundant, in contrast with the counties where they are most scarce, vary widely in their use of the new health professionals. Ten of them employ 18 or more (the range is from 18 in Hertford county to 87 in Durham county) while the remaining 15 employ five or fewer. Therefore, while 53.9 percent of midlevel practitioners practice in the counties with the largest supply of primary care physicians, there are many counties with a good supply of primary care physicians that do not employ midlevel practitioners. This is particularly true of counties in the northeastern and southwestern corners of the state. Counties having an abundance of both primary care physicians and midlevel practitioners are those that house major cities, large medical centers, or both: Buncombe (Mountain AHEC), Burke (1,228 psychiatric hospital beds), Forsyth, Guilford, Mecklenburg, New Hanover (New Hanover Memorial), Pitt (Pitt Memorial and Eastern AHEC) and

the Triangle (Durham, Orange and Wake).

These data show that midlevel practitioners in North Carolina are employed not in the counties where primary care physicians are scarce but in counties that are already served by large teaching medical centers. In fact, the correlation between the number of midlevel practitioners and the number of primary care physicians, not adjusted for the size of the population they serve, is .896. However, it remains to be discovered whether this pattern reflects the location choices of the new practitioners or a limited opportunity structure for them outside the areas where health care innovations are to be expected.

#### References

- 1. Sultz HA et al. Nurse practitioners: an overview of nurses in the expanded role, In Bliss AA, Cohen ED (eds), The new health professionals. Germantown, MD: Aspen Systems Corporation, 1977.
- 2. American Medical Association. Physician characteristics and distribution, 1982 edition. Chicago: Survey and Data Resources, American Medical Association. 1983.
- 3. This number increased over 100 percent between 1978 and 1983.
- 4 North Carolina Health Manpower file. Health Service Research Center, University of North Carolina at Chapel Hill, Chase Hall 132-A, Chapel Hill, North Carolina 27514. Telephone: 919/966-5011
- 5. Primary care physicians are those in general practice, family practice, internal medicine, pediatrics, and obstetrics/gynecology.



#### **Practical information** on the medical aspects of fitness and exercise.

Tennis elbow: Joint resolution by conservative treatment.

Hypertrophic cardiomyopathy and the athlete.

Effects of sunscreen use during exercise in the heat.

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How I manage ingrown toenails.



#### Glipizide and Glyburide

Joanne Kure, Pharm.D.

THE first generation sulfonylureas (tolbutamide, chlorpropamide, tolazamide and acetohexamide) have been used for nearly three decades in the treatment of noninsulin dependent diabetes mellitus (NIDDM). Recently, new, more potent sulfonylureas (glipizide and glyburide) have become commercially available in the United States. Glipizide (Glucotrol) and glyburide (DiaBeta, Micronase) are referred to as "second generation" sulfonylureas and possess distinctive pharmacokinetic and pharmacologic characteristics. This article reviews the pharmacology, pharmacokinetics and therapeutic use of glipizide and glyburide in the treatment of NIDDM.

#### Pharmacology

Although sulfonylureas have been used for over thirty years, their exact mechanism of action is still unclear. These compounds require functioning pancreatic tissue in order to produce hypoglycemia. Sulfonylureas acutely stimulate the release of insulin from the beta-cells in the pancreas. <sup>1-3</sup> In vitro studies suggest that these compounds interact with the beta-cell membrane to stimulate adenyl cyclase and inhibit phosphodiesterases, resulting in insulin release. <sup>4</sup> However, current evidence does not support the view that a change in cAMP concentration stimulates insulin secretion. <sup>5</sup> Henquin has proposed that insulin secretion is mediated by the enhancement of calcium flux that results from depolarization of beta-cell membrane. <sup>6</sup>

Increased glucose-stimulated insulin release has been noted after short-term therapy. <sup>1,7</sup> However, with long-term use, fasting insulin levels were found to be slightly increased or decreased (back to pretreatment level) while maintaining glucose tolerance. <sup>8,9</sup> This suggests that sulfonylureas may induce hypoglycemia by extrapancreatic effects. <sup>1,7,10</sup>

NIDDM patients have been found to have normal or slightly increased fasting insulin levels.<sup>2</sup> A resistance to insulin at the peripheral cellular level may contribute to the pathogenesis of NIDDM.<sup>2</sup> There exist a number of theories in attempts to explain insulin resistance. Some of the extrapancreatic effects are enhanced hepatic synthesis of glucose, <sup>11, 12</sup> impaired hepatic extraction of glucose, <sup>11</sup> decreased binding to insulin receptors (prereceptor activity), <sup>2, 7, 11</sup> and decreased intracellular glucose metabolism (post-receptor activity), <sup>2, 7, 11</sup> Kloterman et al concluded glyburide enhanced the peripheral effects of insulin by acting primarily at correcting post-receptor defects, re-

ducing basal glucose output from the liver and increasing insulin binding.<sup>7</sup> Many of the same conclusions were reached by other authors and investigators.<sup>2, 13</sup> The pharmacology has been found to be similar for both the first and second generation sulfonylureas.

It has been postulated that decreased serum insulin levels may further increase the insulin binding capacity, while insulin levels are found to be inversely proportional to the number of insulin receptor binding sites. <sup>14, 15</sup> However, this is not found in all NIDDM patients. <sup>14</sup>

#### **Pharmacokinetics**

Similar to other sulfonylureas, glyburide and glipizide are well absorbed following oral administration (table 1). Glipizide produces a peak serum concentration approximately 1-2 hours after administration, while glyburide peaks within 2-3 hours. <sup>16, 17</sup> Studies with healthy volunteers and NIDDM subjects have found a delayed absorption of glipizide due to food; <sup>18,19</sup> therefore, it is recommended that glipizide be given 30 minutes prior to the meal. In contrast, glyburide's absorption is not affected by food. <sup>20</sup> Patients taking glyburide 30 minutes prior to breakfast were found to have a greater reduction in blood glucose. <sup>21</sup>

The second generation sulfonylureas are found to have small volumes of distribution due to the high degree of protein binding. These agents are extensively bound to albumin (98-99%) by nonionic forces. <sup>22, 23</sup>

Both drugs undergo extensive metabolism by the liver, each producing two major metabolites by hydroxylation (4-transhydroxy and 3-cishydroxy). <sup>24, 25</sup> Glyburide is almost completely metabolized with no unchanged drug recovered in the urine and only 4-6% unchanged drug found in the feces after 24 hours. <sup>26</sup> The major metabolites of glyburide were found to have little or no activity. <sup>25</sup> Glipizide is almost entirely metabolized with 3-10% recovered unchanged in the urine during the first 24 hours. <sup>26</sup> All glipizide metabolites were found to be essentially inactive. <sup>24</sup> The inactive nature of the metabolites is important to patients with renal insufficiency to decrease (but not eliminate) the potential for accumulating metabolites which may result in the development of hypoglycemia. <sup>3, 5</sup>

Following the administration of radio-labeled glyburide, approximately 50% of the drug was recovered in the urine and 50% in the feces. 25 Approximately 65-85% of glipizide was recovered in the urine, 3-10% of which was eliminated unchanged, and approximately 15% was fecal elimination. 16, 26 The elimination half-lives for glyburide and glipizide are 6-12 hours and 2-7 hours, respectively. 16, 26 The terminal half-life of both drugs increases with multiple dosing due to accumulation of the drug. 16, 22 Though the

From the Department of Pharmacy, Duke University Medical Center, Durham 27710. References available from NCMJ editorial office.

Table 1
Comparison of Pharmacokinetic Properties of Oral Sulfonylureas<sup>52</sup>

Drug	Average elimination half-life (hr)	Duration of action (hr)	Daily dosage range (mg)	Doses required per day	Route of elimination
Tolbutamide	7	6-10	1000-3000	2-3	Hepatic metabolism; renal excretion of less active metabolites
Acetohexamide	1.5	8-12	100-1500	2	Hepatic metabolism; active metabolite (hydroxyhexamide) has half-life of 5 hr and is excreted renally
Tolazamide	7	12-18	100-1000	1-2	Hepatic metabolism; renal excretion of less active metabolites
Chlorpropamide	35	24-72	100-500	1	80% hepatic metabolism; renal excretion of parent drug and less active metabolites
Glyburide	7-10	16+	2.5-20	1-2	Hepatic metabolism; renal excretion of less active metabolites
Glipizide	2-7	6	2.5-40	1-2	Hepatic metabolism; renal excretion of inactive metabolites

half-lives of these drugs are relatively short, the duration of action allows for once daily dosing in most people.<sup>27-29</sup>

Since these drugs are extensively metabolized and highly excreted renally, precautions should be used when these agents are administered to patients with renal and/or hepatic insufficiency.3, 27-29 lt is recommended that individuals with impaired renal function be started on low initial doses with slow titration.27-30 Diabetics with renal insufficiency are more likely to experience hypoglycemic episodes due to decreased renal elimination and accumulation of the sulfonylureas and their metabolites.22 Pharmacokinetic data with glyburide and glipizide in renal insufficiency are limited. Preliminary studies have shown prolonged half-lives of sulfonylurea metabolites in patients with renal insufficiency.30-32 However, this accumulation may not be clinically significant, since second generation sulfonylureas are metabolized to substances with little or no activity.24, 25 Patients with mild to moderate renal insufficiency should be started at low doses and titration done slowly and cautiously. 27-29 These drugs should not be used in patients with severe renal impairment (GFR<30) ml/min).23,31

#### Clinical Efficacy

All sulfonylureas acutely lower blood glucose in NIDDM.<sup>3, 5</sup> However, the long term glucose lowering potential is in question. Although many studies have been done looking at the clinical efficacy of prolonged treatment of NIDDM with sulfonylurea agents, <sup>5, 33-36</sup> the majority of them were poorly designed (their limitations summarized by Jackson and Bressler).<sup>3</sup> There is no evidence that prophylactic treatment of asymptomatic NIDDM with sulfonylureas either restores to normal or prevents deterioration of carbohydrate tolerance.<sup>5, 37</sup> Studies have shown that patient selection is an important factor influencing the long term efficacy of oral hypoglycemic therapy.<sup>3, 37, 38</sup> Patients with the following criteria have been found to have a greater success rate:

1) age of onset after 40 years of age

2) duration of disease < 5 years before initiation of therapy

3) above normal weight at the time of presentation

4) absence of kctoacidosis

5) fasting blood glucose < 200 mg/dl

6) insulin requirements less than 20-30 units per day

Glyburide and glipizide have been found to be significantly more effective than placebo in controlled, doubleblind studies.36,39 The efficacy of these drugs is generally comparable with that found with first generation agents. 3, 40-43 Glipizide has been compared with tolbutamide in two studies. Twenty-nine patients received both drugs in a crossover fashion for 10-30 days; the mean fasting blood glucose and post-prandial blood glucose concentrations were significantly lower with glipizide therapy.46 Fuchs concluded that glipizide (average dose 8.8) mg) was at least as effective as tolbutamide (average dose 1986 mg) in reducing blood glucose concentrations. 41 Glyburide and tolazamide have shown comparable efficacy in two double-blind, controlled studies. 42, 47 In a five year study of six NIDDM subjects taking glyburide (2.5-5 mg) and seven NIDDM subjects taking tolazamide (125-250 mg), the fasting blood glucose concentrations for both drugs generally ranged between 80 and 110 mg/dl.<sup>47</sup> Studies comparing the efficacy of chlorpropamide with glyburide and glipizide have yielded varying results. Clark et al reported that the overall primary failure rate in 285 diet failed NIDDM subjects was significantly lower with chlorpropamide than with glyburide.44 In contrast, 60 Nigerian subjects with either new onset NIDDM or previous chlorpropamide treatment were given a trial of either glipizide, glyburide or chlorpropamide. Chlorpropamide was found to be less potent and slower to achieve adequate control of blood glucose when compared with the other agents. 43 Bandisode and Boshell reported that patients who failed to respond to maximum doses of glipizide (20-40) mg) did not respond to maximum doses of chlorpropamide

and vice versa.45

Glipizide and glyburide are comparable in terms of their ability to control fasting blood glucose in NIDDM.39 In a double-blind, crossover study, Blohme and Waldstrom compared the efficacy of glipizide and glyburide in NIDDM.<sup>48</sup> They concluded that glyburide had a more prolonged, stronger blood glucose lowering effect, whereas glipizide had a quicker onset of action. 48 Although the differences were statistically significant, they were marginal from the clinical point of view.48

Sulfonylureas have been found to enhance the action of insulin. The mechanism seems to be an enhanced pancreatic insulin secretion, not the extrapancreatic effects. 49-50 A number of studies have investigated the effect of adding glyburide, glipizide or other sulfonylureas to insulin in NIDDM patients who no longer respond adequately to insulin alone. 49-51 The majority of these studies found an overall improvement in diabetic control.

#### **Adverse Drug Reactions**

The side effect profile of the second generation oral hypoglycemic agents is similar to that found with first generation agents.3 The overall incidence of adverse effects for the first generation sulfonylureas range from 3.2% to 4.1%.3, 23 The majority of NIDDM patients are able to tolerate recommended doses of sulfonylureas without experiencing adverse effects.

The most common adverse effects are the nonspecific gastrointestinal complaints, including symptoms such as nausea, vomiting, heartburn, flatulence, diarrhea, constipation and a metallic taste.5, 52 Other non-specific effects include headache, tiredness and paresthesias, which are dose-related, transient and respond to dose reduction. 5, 52 Dermatologic reactions can also occur, presenting as pruritus, urticaria, erythema and morbilliform or maculopapular rash.5,52 Elevations in liver function tests have been reported, but cases of jaundice are rare. 3, 23, 54

The issue of long-term cardiovascular toxicity remains highly controversial. The University Group Diabetes Program (UGDP), a multicenter trial (1960), was to determine whether or not control of blood glucose levels helps to prevent or delay vascular disease in non-insulin requiring diabetic patients.56 The UGDP study found that fixed tolbutamide doses resulted in increased cardiovascular mortality.56 The conclusions from this study have been debated for the last decade, with serious questions regarding the monitoring of patients, patient assignment to treatment

Drugs Directly or Indirectly Affecting the Hypoglycemic Action of Sultonylureas52

Drugs that	Drugs that
increase	decrease
hypoglycemic	hypoglycemic
effect	effect
Ethanol -blockers Chloramphenicol Coumarin anticoagulants Insulin Phenylbutazone Salicylates Sulfonamides	Corticosteroids Diazoxide Ephedrine Epinephrine Ethacrynic acid Furosemide Phenobarbital Rifampin

groups and the actual data themselves. 57, 58 As a result of the conclusions drawn from the UGDP, the FDA requires all sulfonylurea package inserts to contain a bold-faced warning addressing the increased risks of cardiovascular mortality associated with the administration of oral hypoglycemic agents. 27, 28, 29 The current status of the oral hypoglycemic agents in the management of diabetes has been reviewed by the American Diabetes Association. The policy reinforces the need for an individualized approach, emphasizing the importance of nutrition, exercise and the use of sulfonylureas as adjunctive therapy when indicated.<sup>59</sup> Judgment on the possible adverse cardiovascular effects of sulfonylurea therapy was deferred pending further accumulation of definitive data.

Hypoglycemia is probably the most frequent serious effect of the sulfonylureas, with a reported range of 1-5%.3, 23 In a review of 778 cases of drug-induced hypoglycemic coma, Seltzer found sulfonylureas were involved in 69% of the cases. 60 Chlorpropamide, the longest acting agent, accounted for the majority of the cases; glyburide was implicated even at low doses. 60 The Swedish Adverse Reactions Advisory Committee reviewed and published all glyburide-associated hypoglycemic reactions from 1965 to 1983.61 There were 57 reported cases with a median age of 85 years; 8 of 40 cases occurred during the first month of treatment. The incidence of hypoglycemia with more potent agents (glyburide and glipizide) may be falsely elevated due to prescribers' unfamiliarity with these agents.1

A unique side effect of glyburide and glipizide is a mild

Table 3	
Dosing of Glipizio	le and Glyburide <sup>27-29</sup>

	Glyburide
e range 2.5-40 mg	1.25-20 mg
on of action >6 hr (once daily of	
>15 mg (twice dail	y dosing) 10 mg (twice daily dosing)
dosage 5.0 mg	2.5-5.0 mg
lose for elderly, 2.5 mg	1.25 mg

Table 4
Cost Comparison of Oral Sulfonylureas Based on Approximately Equivalent Doses<sup>52</sup>

Generic name	Trade name	Manufacturer	Equivalent doses (mg)	Dose* (\$)
Acetohexamide	Dymelor	Lilly	500-750	0.23-0.35
Chlorpropamide	Diabinese	Pfizer	250-375	0.26-0.42
Glipizide	Glucotrol	Roerig	5	0.16
Glyburide	DiaBeta	Hoechst-Roussel	5	0.25
Glyburide	Micronase	Upjohn	5	0.25
Tolazamide	Tolinase	Upjohn	250-375	0.24-0.38
Tolbutamide	Orinase	Upjohn	1000-1500	0.26-0.48

Based on equivalent therapeutic doses (mg) using average wholesale prices as quoted in Redbook-1984 (when available)

diuretic action.<sup>53</sup> This currently has no proven clinical utility; however, it may prove useful in a patient with concurrent water retention. Glyburide and glipizide have not been found to cause a disulfiram reaction, SIADH nor do they affect serum uric acid concentrations.<sup>1,53,54</sup>

#### **Drug Interactions**

There are many drugs that could interact with sulfonylureas due to their extensive metabolism and high degree of protein binding. 3, 55 There is little evidence to support the majority of the interactions, and even less information regarding drug interactions associated with second generation sulfonylureas. 3, 55 However, there seems to be little difference between the drug interactions seen with the older agents and those seen with the second generation sulfonylureas<sup>27-29</sup> (see table 2).

Unlike the first generation sulfonylureas, glipizide and glyburide appear to be bound to albumin by non-ionic forces. 62, 63 Results of an *in vitro* study using human and bovine serum albumin indicated that glyburide was much less susceptible to displacement from albumin by several acidic drugs (phenylbutazone, warfarin and salicylates) than tolbutamide and possibly chlorpropamide. 64 If *in vivo* data are consistent with the *in vitro* results, then glyburide and glipizide may be used in conjunction with other highly protein-bound drugs.

#### Dosing and Administration

The second generation sulfonylureas are approximately 100 times more potent than the first generation agents, 1, 3 with glyburide being slightly more potent than glipizide. 48

The relatively long duration of action of glyburide allows for once-daily administration. The manufacturers recommend that the dose be given with breakfast or 30 minutes before the meal. <sup>27, 28</sup> Twice-daily dosing may be indicated when the daily dose exceeds 10 mg. <sup>27, 28</sup> Glipizide's duration of action is slightly shorter than that of glyburide, but can still be given as a once daily dose before breakfast. <sup>29</sup> Daily doses exceeding 15 mg should be divided. <sup>29</sup>

The dosing of glyburide and glipizide should be individualized for each patient (see table 3). An initial starting dose of 2.5-5.0 mg once daily is recommended for glyburide and 5.0 mg once daily for glipizide. Elderly patients or patients with hepatic or renal insufficiency should be

started at lower doses (i.e., 1.25 mg and 2.5 mg, respectively). The recommended maximum daily doses are 20 mg of glyburide and 40 mg of glipizide.<sup>27-29</sup> Dosage increases should only occur when the reduction of blood glucose has stabilized (no more than weekly), since the biological half life of both drugs is longer than the elimination half life, and may accumulate after multiple doses.<sup>22, 27, 28, 29</sup>

When transferring patients maintained on other oral sulfonylurea agents (with the exception of chlorpropamide) to glipizide or glyburide, no drug free period or loading dose is necessary. The patient should be started on a dose that is approximately equivalent (see table 4). The transition from chlorpropamide should be made more cautiously (particularly during the first few weeks), due to chlorpropamide's long duration of action and the potential for additive hypoglycemia. 27-29

When transferring from insulin to glipizide or glyburide, the daily insulin dose should be considered when selecting the initial sulfonylurea dose. Patients with low insulin requirements (10-20 units per day) can be switched directly.<sup>27, 28, 29</sup> However, the transition should be made more slowly when daily insulin requirements are greater than 40 units.<sup>21, 28, 29</sup> In these cases, the insulin dose should be decreased by half and the appropriate dose of a second generation sulfonylurea should be started<sup>27,29</sup> (see table 5). When the patient is stabilized, the insulin can be discontinued and the dosage of the sulfonylurea should be titrated accordingly.<sup>1, 27,29</sup>

Glyburide is marketed as Micronase (Upjohn) and DiaBeta (Hoechst) in 1.25 mg, 2.5 mg and 5.0 mg

Table 5
Transferring from Insulin to Glyburide or Glipizide<sup>27-28</sup>

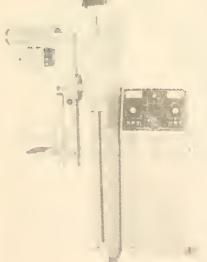
Daily Insulin requirements	Glipizide	Glyburide
10-20 units	5 mg	2.5-5 mg
20-40 units	5 mg*	2.5-5 mg
40 units	· ·	5 mg*

strengths.<sup>27, 28</sup> Glipizide is marketed as Glucotrol (Roerig) in 5.0 mg and 10 mg tablet strengths.29

#### Conclusion

Both glipizide and glyburide are approved by the FDA as an adjunct to diet to lower the blood glucose in patients with NIDDM, when diet alone is ineffective. Although glipizide and glyburide do not appear to have striking therapeutic advantages over the first generation sulfonylureas, they do exhibit some unique properties. They are more potent than the first generation sulfonylureas, with a duration of action such that once-daily dosing is effective in most patients. These drugs should be avoided or cautiously used (in low doses) in patients with renal insufficiency until more experience with such patients is obtained, since their metabolites have little or no activity. Glipizide and glyburide are non-ionically bound to plasma proteins, potentially decreasing plasma protein binding displacement by other agents. Some of these properties may provide alternatives to patients who do not have satisfactory responses to other agents.

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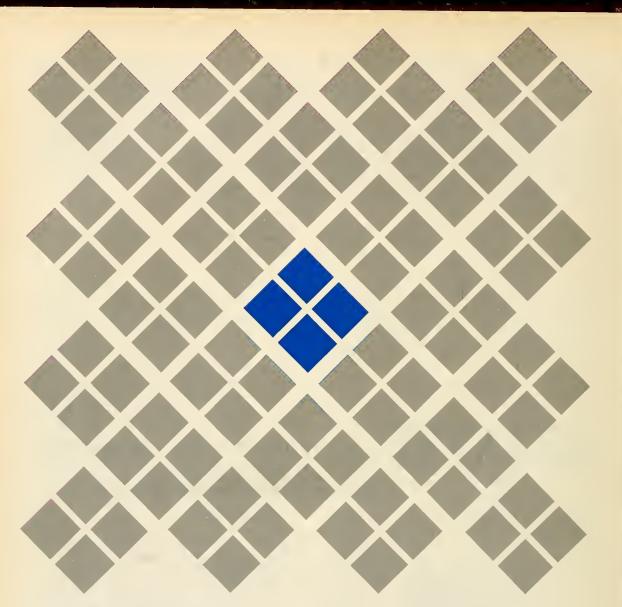
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Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

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Credit:

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#### March 18-22

Infection Control Workshop

Place: Chapel Hill

Info: W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118

#### March 19

Oncology for the Practicing Physician

Place: Sanford

Credit:

2 hours Category I AMA; AAFP R. S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

#### March 22

Seventh Annual Pulmonary Disease Update

Place: Greenville

Credit: 6.5 hours Category 1 AMA

Fee: \$55

Info: Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/

758-5200, ext. 208

#### April 3

22nd Annual Spring Cardiovascular Symposium

Place: Chapel Hill

Credit: Info:

8 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878

#### April 3-5

Rehabilitation Conference: Management of Spinal Cord Injury

Place: Greenville Infa:

Office of CME, ECU, Box 7224, Greenville 27835-7224. 919/758-5200, ext. 208

#### April 4-5

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Chapel Hill

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Place: Durham

Credit: 8 hours Category I AMA

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Credit:

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Info: Dr. Frederick W. Kremkau, Center for Medical Ultrasound,

Bowman Gray, Winston-Salem 27103, 919/748-4505

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April 22-26

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Place: Chapel Hill

Credit: 35 hours Category 1 AMA Info:

W. B. Wood, M.D.,, 231 MacNider 202H, UNC, Chapel Hill 27514, 919/962-2118

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Credit:

10 hours Category I AMA, 9 hours AAFP Department of Pediatrics, Charlotte Memorial Hospital, Box 32861, Charlotte 28232. 704/338-3156

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Place: Durham

Credit:

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teins and Their Receptors Place: Greenville

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Place.

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June 7

Short Course in Diagnostic Imaging: Body II

Place: Durham

Credit: 8 hours Category 1 AMA

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Fee: \$350

Info: W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill

27514. 919/962-2118

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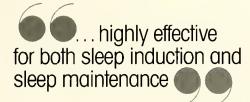
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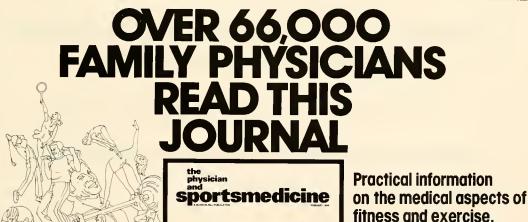
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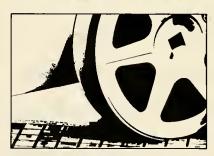
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## The Neonatal Status Score: A Predictor of Mortality

Rita L. Saldanha, M.D., Grant W. Somes, Ph.D., Cathy Conklin, R.N., and Arthur E. Kopelman, M.D.

A LTHOUGH sick and premature newborns should optimally be delivered at a hospital with a tertiary level neonatal unit, this is not always possible. The primary care physician must then effectively resuscitate and stabilize the infant prior to transfer to a neonatal intensive care unit. In turn, neonatologists at the neonatal intensive care unit have the responsibility of helping to train physicians and nurses at the referring hospitals to be prepared to stabilize critically ill neonates.

Our neonatal intensive care unit was developed in 1978 to serve 29 counties in a rural region of eastern North Carolina with 21 relatively small community hospitals. We needed an objective measure of the adequacy of neonatal stabilization done at each of our referring hospitals. This would provide us with information regarding their strengths and weaknesses. An objective score could also be used to determine the degree that neonatal outreach educational programs improved neonatal resuscitation and stabilization at community hospitals.

We used a Neonatal Status Score similar to, but expanded from, the one developed by Kanto which had been shown to predict survival. 1. 2 Our score, which measured the adequacy of stabilization for eight different variables, was recorded when our transport team first viewed the infants at the referring hospital and again immediately on arrival at our neonatal intensive care unit.

#### Subjects and Methods

When our neonatal intensive care program was developed in 1978, this region had experienced a neonatal mortality rate of 11.9/1,000 live births, well above the national average. As we began an ambulance-based neonatal transport program, it was clear that there were variations in the adequacy of neonatal stabilization prior to transport between the referring hospitals.

This paper describes the neonatal status score values found in the first 205 consecutive infants transported to our neonatal intensive care unit prior to implementation of our outreach education program, and reports on the association between that score and infant survival. The paper also compares transports done by neonatal nurse clinicians and pediatric residents. The person going on the transport was assigned by a previously set schedule.

#### From the Departments of Pediatrics and Allied Health, East Carolina University School of Medicine, Greenville 27834.

#### Neonatal Status Score

A neonatal status score was assigned to each infant (table 1). The score assigns a value of 0, 1, or 2 for each of eight variables, similar to the weighting of the Apgar score. The highest possible score is 16, and lowest is zero. For each parameter 2 is the best score, 1 is intermediate, and 0 is the worst score. The eight variables scored are: temperature, heart rate, respirations, color, blood pressure, perfusion (assessed by capillary refill), responsiveness (assessed by response to painful stimuli applied to feet) and dextrostix. These eight were chosen because we felt they were important indicators of adequate vs inadequate infant stabilization.

The neonatal status score was first recorded  $(T_1)$ , when our transport team viewed the infant at the referring hospital. We believed that it reflected the adequacy of stabilization measures up to that point. The second score, assigned by the same team immediately when the infant arrived in our neonatal intensive care unit  $(T_2)$ , reflected the infant's condition following further stabilization measures instituted by our transport team and the ambulance transport to our unit.

Neonatal status scores assigned at each point in time were compared by Kendall tau correlation with survival measured as discharge from the neonatal intensive care unit or death in the neonatal intensive care unit. Neonatal status scores at  $T_1$  and  $T_2$  were compared by chi-square analysis to see if there was a difference between infants transported by neonatal nurse clinicians or by pediatric residents.

#### Results

Two hundred and five neonates were transported from our 21 referring hospitals to our neonatal intensive care unit during the period from September 1980 through December 1982. The mean birth weight was 2067 g (range 630 g to 4090 g), and the mean gestational age was 34.6 weeks (range 25-43 weeks). One hundred seventeen of the 205 infants were male, and 110 were black. Table 2 shows the primary admitting diagnoses.

Neonatal Status Score. The neonatal status scores at  $T_1$  and  $T_2$  for all 205 infants are shown in table 3, as well as the scores for the subgroups of infants >1500 g and <1500 g. In all groups, the neonatal status scores were higher at  $T_2$ . This reached significance at p <0.001 for all infants transported and for the subgroup of infants <1500 g, and at p <0.05 for infants weighing >1500 g.

Table 1.		
Neonatal	Status	Score

Variable	2	Score 1	0
Temp (°F)	97.5-99	>99	<97.5
Heart rate	100-180	>180	<100
Respirations	No distress, <60/min	Moderate distress, > 60/min, grunting, retrac- tion	Severe distress, apnea, gasping, IPPV, bagging
Color	Pink	Dusky	Cyanotic
Systolic BP (mm Hg)	>40	30-40	<30
Perfusion	Capillary refill < 1 second	Capillary refill > 1 second	Mottling, obviously poor perfusion
Response to noxious stimuli	Activity, withdraws	Slow response	No response
Dextrostix (mg%)	45-130	>130	0-45

There were no deaths during transport, but 35 of the 205 infants died during their hospital stay; 31 died in the first 28 days. The neonatal status score at both  $T_1$  and  $T_2$  correlated strongly with survival, p < 0.001. The very strong correlations between low neonatal status score at either  $T_1$  or  $T_2$  and mortality is shown graphically in figure 1 where the infants are divided into subgroups with low (0-9), middle range (10-12), or high (13-16) neonatal status scores. The mortality for infants with a low neonatal status score at  $T_1$  was 36.6 percent while it rose to 53.3 percent if the neonatal status score was still low at  $T_2$ .

Neonatal Nurse Clinician vs Pediatric Resident Transports. Neonatal nurse clinicians supervised 162 of the transports while pediatric residents handled 43. There were no differences in the neonatal status score at either  $T_1$  or  $T_2$  and no significant difference in the scores between  $T_1$  and  $T_2$  for either group. The mortality of infants transported by nurse clinicians and pediatric residents also did not differ significantly, 15 percent vs 25 percent.

#### Discussion

Neonatal care has been regionalized and sick neonates transferred to tertiary level neonatal intensive care units for over three decades.<sup>3</sup> In establishing a new neonatal intensive care unit in a previously underserved rural area, we developed a simple score which could help us to evaluate the adequacy of initial neonatal stabilization done at community hospitals.

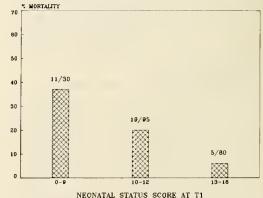
The neonatal status score described in this article gives each infant a weighted score for each of eight parameters

Table 2 Admitting Diagnoses Respiratory distress Bowel obstruction syndrome 103 3 Esophageal atresia Asphyxia Congenital heart disease 4 Sepsis/pneumonia 36 Other congenital Meconium aspiration 9 malformations & Persistent pulmonary miscellaneous 12 hypertension Diaphragmatic hernia 3

(table 1). We recognized that the criteria for assigning a value for each of these parameters were somewhat arbitrary, but these clinical observations were the basis for the infant assessments we had taught our transport personnel and would subsequently include in our outreach education efforts. The scores could be given in a few minutes, and the personnel scoring the infant would do so while evaluating the infant's condition and determining what additional care was needed. It was also obvious that, to at least some extent, a low neonatal status score would be seen in more critically ill infants as well as those who had been less adequately stabilized.

A low neonatal status score at  $T_1$  reflects both the adequacy or inadequacy of initial stabilization by personnel at the referring hospital and the severity of the infant's illnesses. A low neonatal status score at  $T_1$  was found to correlate very strongly with mortality, p <0.0001 (figure 1).

The neonatal status score at  $T_2$  reflects the success of further stabilization by our transport team as well as possible detrimental effects of ambulance transport an average of 55.1 ( $\pm$  22.2) miles to our neonatal intensive care unit. The fact that the neonatal status score at  $T_2$  was higher than at  $T_1$  (13.8 vs 12.3, p <0.001) strongly suggests that



**Figure 1.** The mortality of patients with neonatal status scores at  $T_D$  divided into three arbitrary groups.

Table 3

Comparison of Neonatal Status Scores at T<sub>1</sub> and T<sub>2</sub> by Birthweight

	N	Т,	T <sub>2</sub>	$T_2 > T_1$
All infants	205	12.3 ± 2.9	13.8 ± 2.2	p < 0.001
Infants ≥ 1500	144	$12.7 \pm 2.5$	$13.9 \pm 2.1$	p < 0.05
Infants < 1500 g	61	11.6 ± 3.5*	$13.5 \pm 2.4^{+}$	p < 0.001

Comparison of neonatal status scores (mean  $\pm$  SD) for all transported infants and for infants greater than and less than 1500 g. The p values at the right show that there is a significant increase at  $T_2$  compared with  $T_1$ .

\*The neonatal status score at  $T_1$  is lower for infants < 1500 g than for larger infants, p< 0.01.

\*There is no significant difference between the neonatal status score for the subgroups at T2.

our transport teams were successful at improving the infants' clinical condition, and that stabilization by personnel at the referring hospitals was not optimal. We would not expect the ambulance trip per se to improve the infant's status and most neonatal diseases (RDS, sepsis, etc) would not be expected to spontaneously improve during the time our team stabilized and transported the infants. A low neonatal status score at  $T_2$  also correlated very closely with subsequent mortality, p < 0.0001. Over 50 percent of the infants with a neonatal status score of 9 or less at  $T_2$  died (figure 2). This high mortality is not unexpected since the

**Figure 2.** The mortality of patients with neonatal status scores at T<sub>2</sub>, divided into three arbitrary groups.

infants' clinical status remained poor following stabilization efforts by our transport teams.

Low birth weight is known to correlate with neonatal mortality. In our patients low birth weight did not correlate with neonatal status score at either  $T_1$  (p >0.17) or  $T_2$  (p >0.5). Thus the neonatal status score does not simply assign lower scores to more immature infants. The correlation of low birth weight with mortality (p >0.01) was not as strong as the correlation of low neonatal status score at  $T_1$  or  $T_2$  with mortality (p <0.0001 for each).

Patient populations with similar scores are at equivalent risk for neonatal mortality. The outcome of patient populations with similar status scores can then be compared if they receive different forms of care.

As one example of how the neonatal status score might be used to compare groups of neonates, we compared 162 neonates transported by neonatal nurse clinicians with 43 infants transported by pediatric residents. Neonatal status scores at T<sub>1</sub> were similar for both groups (12 vs 11), indicating that both groups of infants were at equal risk for neonatal mortality. The neonatal status scores at T<sub>2</sub> were also equal (13 vs 13). Thus, beginning with equally sick (at risk for mortality) infants, neonatal nurse clinicians and pediatric residents performed equally well at further stabilizing and transporting the infants.

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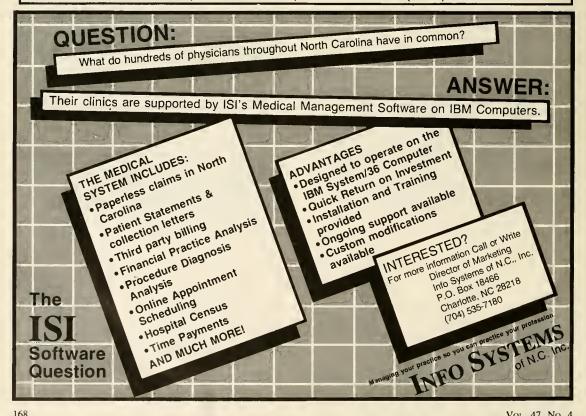
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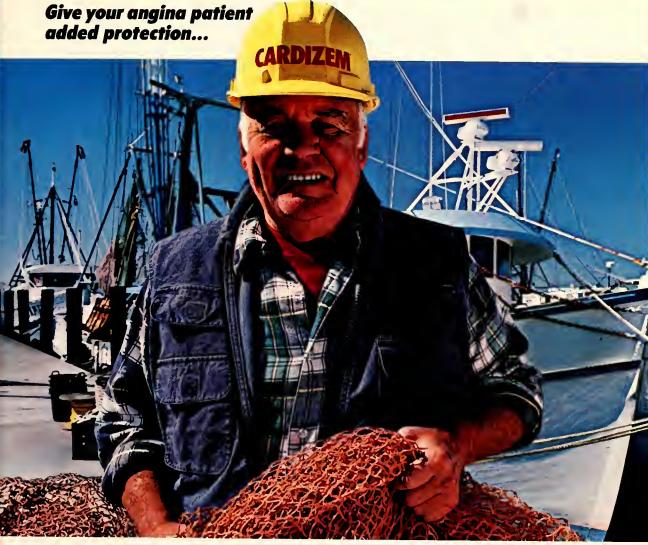
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## CARDIZEM: FEWER SIDE EFFECTS

diltiazem HCI/Marion

- The lowest incidence of side effects among the calcium channel blockers'
- An exceptionally safe choice for angina patients with coexisting hypertension, diabetes, asthma, or COPD<sup>1-3</sup>
- Proven efficacy when used alone in angina 1.4.6
- Compatible with both beta-blockers and nitrates'

Please see brief summary of prescribing information on the next page.



### CARDIZEM® 60 mg tid diltiazem HCI/Marion

#### FEWER SIDE EFFECTS IN ANTIANGINAL THERAPY

CARDIZEM® (diltrazem hydrochlonde) is a calcium ion influx inhibifor (slow channel blocker or calcium antagonist)

#### INDICATIONS AND USAGE

- Angina Pectoris Bue to Coronary Artery Spasm. CARDIZEM is indicated in the treatment of angina pectors due to coronary artery spasm. CARDIZEM has been shown effective in the fleat-ment of spontaneous coronary artery spasm presenting as Prinz-metal's variant angina (resting angina with 51-segment elevation occurrent during afforks).
- metals variant aigma tresting angina with 51-segment elevation occurring during affacks).

  2 thronic Stable Angina (Classic Effort-Associated Angina). CARDIZEM is indicated in the management of chronic stable angina. CABDIZEM has been effective in controlled trials in reducing angina frequency and increasing exercise olerance. There are no controlled studies of the effectiveness of the concomi-

tant use of diffiazem and beta-blockers or of the safety of this combination in patients with impaired ventricular function or conduction abnormalities

CARDIZEM is contraindicated in (1) nations with sick sinus syn CARDIZEM is contaminated in (1) patients and site sites a from except in the presence of a functioning ventricular pacemaker, (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm Hg systolic).

#### WARNINGS

- 1 Cardiac Conduction. CARDIZEM prolongs AV node refractory Cardiac Conduction. CARDIZEM prolongs AV node refractory periods without significantly prolonging smus node recovery time, except in patients with sick smus syndrome. This effect may rarely result in abnormally slow heart rates (particularly in patients with sick smus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Communitant use of dittazem with beta-blockers or digitalist may result in additive effects on cardiac conduction A patient with Prommetal's angian developed periods of asystole (2 to 5 seconds) after a single dose of 60 mp of dithazem.
- 2 Congestive Neart Failure. Although diffrazem has a negative congestive meant railure. Annough cultilazin has a hiegative intotropic effect in isolated animal tissue preparations, hemo-dynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (do/dt) Experience with the use of CARDIZEM alone or in combination with beta blockers in patients with impaired ventricular function is very limited. Cau-
- tion should be exercised when using the drug in such patients

  3 Hypotension. Decreases in blood pressure associated with
  CARDIZEM therapy may occasionally result in symptomatic
- nypotension

  Acute Nepatic Injury. In rare instances, patients receiving

  CARDIZEM have exhibited reversible acute hepatic injury as
  evidenced by moderate to extreme elevations of liver enzymes. (See PRECAUTIONS and ADVERSE REACTIONS)

#### **PRECAUTIONS**

General. CARDIZEM (diltiazem hydrochloride) is extensively metabo-General. CAROLEM (dilitazem hydrochloride) is extensively metabolized by the liver and excerted by the kidneys and nible. As which any new drug gwen over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subscale and chronic dog and rist studies designed to produce toucity, high doses of dilitazem were associated with hepatic damage, in special subscule hepatic studies, oral doses of 125 mg/lg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/lg, were also associated with hepatic changes, however, these changes were reversible with northined doses.

anges were reversible with continued dosing Grug Interaction. Pharmacologic studies indicate that there may be

or united actions. Print indicating is conduction when using beta blockers or digitals concomitantly with CARDIZEM. (See WARNINGS). Controlled and uncontrolled domesties studies suggest that concomitant use of CARDIZEM and beta-blockers or digitals is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant treatment, particularly in patients with left. ventricular dysfunction or cardiac conduction abnormalities. In healthy

volunteers, dilitazem has been shown to increase serum digoxin levels

up to 20%

Carcinogenesis, Mutagenesis, Impairment of Fertility. A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vito bacterial tests. No intrinsic effect on ferthity was observed in rats. Pregnancy, Category C. Reproduction studies have been conducted.

in mice, rats, and rabbits. Administration of doses ranging from five to ten times greater (on a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and letal lethality. These doses, in some studies, have been reported to cause skeletal abnoruoses, in some studies, have been reported to cause skeeteri abnor-malities. In the perinatal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillbirths at doses of 20 times the human dose

well-controlled studies in pregnant women; therefore, use CARDIZEM (diffragem hydrochloride) in pregnant women only if the potential benefit justifies the potential risk to the felus **Kursing Mothers.** It is not known whether this drug is excreted in

human milk. Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outweigh its potential risks in this

Pediatric Use. Safety and effectiveness in children have not been

#### ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CARDIZEM therapy was not greater than that

reactions reported during CABDIZEM therapy was not greater than that reported during placebo therapy. The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition in many cases, the relationship to CARDIZEM has not been established. The most common occurrences, as well as their frequency of presentation, are edema (2.4%), headache (2.1%), nausea (1.9%), dizziness (1.5%), rash (1.9%), asthema (1.2%), AV block (1.1%), in addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrences. the relative frequency of occurrence

Flushing, arrhythmia, hypotension, bradycardia, palpitalions, congestive heart failure, syncope Cardiovascular Paresthesia, nervousness, somnolence, tremor, Nervous System insomma, hallucinations, and amnesia Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOI, Gastrointestinal SGPT and LDH.

Pruntus, petechiae, urticaria, pholosensitivity Dermatologic Polyuria, nocturia

The following additional experiences have been noted

A patient with Prinzmetal's angina experiencing episodes of vaso-spastic angina developed periods of transient asymptomatic asystole approximately five hours after receiving a single 60-mg dose of

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM erythema multiforme, leukopenia, and extreme elevations of alkaline phosphatases, 2001, SGPT, LDM, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

#### DVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with oral diffrazem has been limited. Single oral doses of 300 mg of CARBIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appro priate supportive measures should be employed in addition to gastric lavage. The following measures may be considered

Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer iso proterenol cautioush

High-Degree

Treat as for bradycardia above Fixed high degree AV block should be treated with cardia

Cardiac Failure

pacing.
Administer inotropic agents (isoproterenol, dopamine, or dobutamine) and diuretics.
Vasopressors (eg. dopamine or levarterenol bilartrate).

Actual treatment and dosage should depend on the seventy of the clinical situation and the judgment and experience of the treating

physician. The oral LDs $_{\rm S}$ 's in nuce and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LDs $_{\rm S}$ 's in these species were 60 and 38 mg/kg, respectively fro oral LDs $_{\rm S}$  in odes is considered to be in excess of 50 mg/kg, while lethality was seen in monkeys at 360 mg/kg. The touck does in znan is not known, but blood levels in excess of 800 ng/ml have not been associated with loxicity

#### **DOSAGE AND ADMINISTRATION**

Section 1 Agria Pectoris Due to Atherosclerotic Coronary Ar-tery Disease or Angina Pectoris at Rest Due to Coronary Artery Spasm. Dosage must be adjusted to each patient's needs. Starting with 30 mg four times doub, before meals and at bedtime, dosage with Ju mg toot times daily, before meals and at bedtime, dosage should be increased gradually (given in divided doses three or four bines daily) at one- to two-day intervals until optimum responses is obtained Athough individual patients may respond to any dos-age level, the average optimum dosage range appears to be 180 to 240 mg/day There are no available data concerning dosage require-ments in patients with impaired renal or hepatic function. If the drug must be used in such palients, titration should be carried out with

- Introlar cauben.

  Concomitant Use With Other Antianginal Agents:

  1 Sublingual NTG may be taken as required to abort acute anginal affacks during CARD/EX Mersey.

  2 Prophylactic Ntrate Therapy CARD/EXM may be salely co-administered with soft- and long acting nitrates, but there have been no controlled studies to evaluate the antianginal effectiveness of this combination. ness of this combination

  3 Beta-blockers. (See WARNINGS and PRECAUTIONS.)

#### HOW SUPPLIED

NOW SUPPLED

CARDIZEM 30-mg lablets are supplied in boffles of 100 (NDC 0088-1271-47) and in Unit Dose Identification Pals of 100 (NDC 0088-1771-49). Each green tablet is engraved with MARION on one side and 1771 engraved on the other CARDIZEM 60-mg scored tablets are supplied in boffles of 100 (NDC 0088-1772-47) and in Unit Dose Identification Pals of 100 (NDC 0088-1772-47) and in Unit Dose Identification Pals of 100 (NDC 0088-1772-47) and in Unit Dose Identification MARION on one side and 1772 on the other Issued 4/1/84

See complete Professional Use Information before prescribing

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## The Impact of Changes in Health Care Finance on Critical Care

Duncan Yaggy, Ph.D., and Phyllis S. Ellenbogen, M.B.A.

THE day of reckoning has dawned.

The effort to control the growth of health care expenditures took so long to get organized that many people thought it would never come. But it has, and the effects are beginning to show. Over the next ten years, the impact will be dramatic. In 1995, the health system we know today will look and work differently. For providers, surviving from now to then is likely to be difficult and to require adaptation to changes that we cannot now imagine.

The pressure to reduce the rate of increase in health care expenditures will be felt late in critical care, perhaps last of all. But it will be felt, and this article considers its impact.

The effort to control health care cost increases began in the early 1970s. At that time we began to see the remarkable effects of the Medicaid and Medicare programs enacted in 1965. On the one hand, the health of the poor and the elderly showed a marked improvement. Infant mortality rates dropped, and life expectancy showed its first real gain in decades. On the other hand, public expenditures for health care grew much faster than anyone had expected, and they seemed certain to continue growing, perhaps even faster.

What with Watergate, the final collapse in Vietnam, the oil crisis of 1974 and other distractions, the growth in health care expenditures did not awaken the public interest it might have, but it got a lot of attention from governments, especially from state governments then teetering on the edge of bankruptcy. It also got attention from thoughtful people in the health care industry, and from employers and insurers concerned about the increases in their costs. Their concern was well placed: between 1960 and 1980, American health care expenditures rose at an average rate of 11.7% per year, significantly faster than the rate of inflation.

As governments were first to feel the pinch, the first efforts at control were regulatory. Three major initiatives were launched:

1. Rate regulation — Price controls were initiated by the federal government and pursued by state governments facing serious financial difficulties (e.g., Massachusetts, New York). Price controls seemed an obvious and easy solution to the problem, for limiting the amounts that doctors and hospitals could charge for each unit of service

would certainly limit the growth in health care expenditures.

Rate regulation enjoyed modest success in several states, and the Carter Administration was inspired to propose federal limits on hospital charges. But the industry beat back the challenge with a "voluntary effort" that was effective so long as rate regulation seemed a genuine threat. With the election in 1980 of a president committed to deregulation, the threat faded, and hospital expenditures resumed their rapid climb.

2. Certificates of need — By the early 1970s it was clear that the nation had tens of thousands more hospital beds than it needed, and this fact drew attention to the supply of health care services and facilities. Some research disclosed that the amount of health care provided varied with the supply of services available. In Massachusetts, where there were relatively more doctors and hospital beds, people were hospitalized more often and for more days than people in California. It was thought that this was the result of the difference in supply. The supply is there, it benefits the providers to have it used, and it gets used. As one critic observed, "a built bed is a filled bed."

Perceiving the connection, Congress passed in 1974 health planning legislation that mandated the states to certify the need for important additions to the supply of health care services and facilities. States were provided funds to initiate certificate of need programs, and they were threatened with the loss of Medicare and Medicaid funds if they failed to implement them. Virtually all the states enacted certificate of need legislation. The laws varied in detail, but they all put the burden of proof on those proposing new or expanded services or facilities: before the state would approve an addition to the supply, the proponent would have to demonstrate the need for it.

Certificate of need sounded like a simple and effective way of controlling the supply of health care services. It was neither. It wasn't simple because it has proven difficult to determine what is needed and what isn't. It wasn't effective either, partly on that account but also because of four other factors:

—The program never attracted the public support that effective regulatory control requires. Certificate of need smacks of rationing, and most Americans weren't ready for that, particularly when there were a lot of experts arguing that it would never work, or that competition would do the same job better by weeding out the inefficient and the unnecessary. In many states, certificate of need controls on hospitals and clinics were more apparent than real.

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—In some places where certificate of need was taken seriously, like Massachusetts, it was already too late. There were already too many doctors, too many hospitals, too many services and facilities of most kinds. Since certificate of need was applied only to new projects, using the process to control the rate of increase in health care costs was a bit like locking the barn door after the horse was gone.

—Over much of the supply, certificate of need exercised no control. It did not control the supply, distribution or activities of doctors, nurses, or other health care professionals. It controlled only the supply of new institutional facilities and services.

—Government agencies denying certificates of need were obliged to act in public hearings, where they could be confronted directly with people whose lives or health, it was alleged, would be threatened or impaired.

Certificate of need programs served to prevent the construction of an even larger supply of hospital beds. But they did very little to prevent rapid increases in expenditures for hospital services or in-hospital rates.

3. As efforts to control the price and supply of health care services fell short, a third strategy was launched: an effort to limit the utilization of health care services. At first, that strategy did not seem to work well either. Professional Standards Review Organizations, which were established in 1972 to review the practice patterns of physicians and to penalize those who made unnecessary use of health care services for their patients, caused a stir, especially among physicians, but they didn't have much effect. By 1980, they were perceived as largely ineffective, and a strong argument was made for the proposition that they cost more to administer than they saved in reimbursements recaptured or denied. As a result, they were nearly abolished.

Whatever their successes, rate regulation, certificate of need, and professional standards review programs did not serve their purpose. Expenditures for health care services continued to rise at a rate substantially greater than inflation through the early 1980s. At the same time, the federal government began to experience deficits so large that they appeared to threaten the entire economy, and the search for ways to control government health care expenditures was intensified.

The problem was to find a means both effective and politically viable. Proposals to reduce the scope or number of services that the government would buy, to increase deductible or co-payment requirements substantially, and to reduce the number of persons eligible for publicly financed health care services were all discussed repeatedly, but none could be enacted. Society and its elected representatives were willing to disapprove new health care programs or the extension of existing services, but they were not ready to take away benefits regarded as entitlements by large numbers of needy citizens. Some other device would have to be found.

The answer came from an unexpected source: research at Yale supported by the Health Care Financing Administration. Dr. John Thompson and his colleagues at the Department of Epidemiology and Public Health were not looking for ways to limit government expenditures for health care. Instead, they were trying to identify the factors

that explain expenditures for hospital services and to understand the relationships between them. Their research led them to a new way of classifying patients' conditions and treatments.

The new scheme consisted of 468 all-inclusive, mutually exclusive "Diagnosis Related Groups" (DRGs). DRGs are categories into which all hospital admissions can be sorted, and the DRG system sorts them in several ways at once:

- 1. According to the part of the body affected. The 468 DRGs are grouped in 23 Major Diagnostic Categories (MDCs), which differentiate between, for example, "diseases and disorders of the nervous system" (MDC 01), "diseases and disorders of the eye" (MDC 02), and "diseases and disorders of the kidney and urinary tract" (MDC 11).
- 2. According to the nature of the treatment provided. Cases involving conditions treated medically are put in different DRGs from cases involving the same conditions treated surgically. Thus, for example, fractured femurs treated surgically are typically placed in DRGs 210 to 212 (Hip and Femur Procedures Except Major Joint), while those treated medically are placed most often in DRG 235 (Fractures of Femur).
- 3. According to other factors, where the Yale research demonstrated that they explained substantial differences in hospital expenditures. The most important factors are the presence of complicating conditions likely to increase the length of stay by one day or more in 75% of cases and the age of the patient. Thus, for example, hospitals are reimbursed more for treating patients in DRG 94 (Pneumothorax with age greater than 69 and/or comorbidities or complications) than for treating patients in DRG 95 (Pneumothorax, with age less than 70 and without comorbidities or complications). Other factors that may affect DRG placement and reimbursement are the patient's sex or discharge status. Thus, burn patients later transferred to another hospital for definitive treatment are grouped in a DRG (456) separate from those DRGs (457-460) used for patients retained for medical or surgical treatment of their burns.

Thompson and his associates were not satisfied simply to identify the factors that explain the differences in hospital expenditures for patients. They also quantified the differences. For each DRG, they developed a "relative weight" that expressed the relationship between expenditures for a patient in that DRG and expenditures for the average hospital patient (relative weight = 1.0000). The relative weights now range from 0.1137 (DRG 382—false labor) to 7.3161 (DRG 104— Cardiac valve procedure with pump and with cardiac catheterization). Using the DRGs to sort patients and relative weights to compare the expenditures made for their care, Thompson and his associates found explanations for differences in hospital expenditures.

But if DRGs and relative weights could be used to explain costs retrospectively, they could also be used to determine prices prospectively, and that is the way they came to be used. Professor Thompson and others could protest that DRGs were not designed for that purpose, but they appeared to serve it so well that the objections were brushed

aside. DRGs and their relative weights were made the basis of reimbursement to hospitals for the services they provided to Medicare patients beginning in October 1983.

Whatever their shortcomings, DRGs and relative weights made possible a Prospective Payment System that offered Congress and the Administration several important advantages:

- 1. It shifted the burden of expenditure control from the government to physicians and hospitals. However the government might manipulate the definitions of "allowable" and "reasonable" costs to limit or reduce payments to hospitals, a payment system that reimbursed hospitals for expenditures in behalf of Medicare patients left the government at the mercy of hospitals and their physicians. A prospective payment system put the shoe on the other foot. Now a hospital would know in advance the amount it would be reimbursed for treating a Medicare patient in a given DRG. If the hospital could keep its expenditures below that level, it could keep the difference as profit; if it allowed expenditures to rise above that level, it would have to absorb the difference as loss.
- 2. It gave the government its first opportunity to budget and control hospital expenditures for Medicare patients. With a payment system designed to reimburse hospital expenditures, the government could only estimate, and usually underestimated, the likely cost of the Medicare program. With a Prospective Payment System that allowed the government to fix in advance the amount that it would pay, and with experience that would soon show how many cases would fall into each DRG each year, the government could determine its likely expenditures during the budget process.
- 3. It promised greater equity. The old cost reimbursement system allowed physicians and hospitals to determine how much they would spend in the treatment of patients, and reimbursed them accordingly. The result was widely differing payments for services to similar patients treated in similar ways. The Prospective Payment System also allowed hospitals to determine how much they would spend for the care of patients, but the amounts they were reimbursed for the care of similar patients treated similarly would vary only to the extent that the government thought it appropriate and fair to let them vary.

Recognizing the dislocations that would result from the immediate implementation of a system that paid all hospitals the same amounts for services provided to similar patients treated similarly, Congress and the Administration agreed on a four-year phase-in of the new system. Payments during the first year were fixed at levels that recognized hospitals' historical costs and other factors that caused variations in their expenditures. During the second, third, and fourth years, allowances for these factors were to be gradually eliminated. At the end of the phase-in period, hospitals would be paid the same rates for similar patients treated similarly, unless the government chose to continue special allowances for differences in capital improvements and involvement in medical training.

4. The new system would give the government a way of encouraging the substitution of new, less expensive treatment modalities for established modalities. If the government wanted to encourage the substitution of coronary

angioplasty for cardiac surgery, for example, it could classify angioplasty in a way that would allow hospitals to earn larger surpluses from the provision of angioplasty than from the provision of cardiac surgery. Reimbursement at the special rate could continue so long as the government thought it necessary to induce the substitution, at which point the classification of angioplasty could be changed.

These advantages were real and significant, and there was not much argument, even from hospitals now suddenly at risk, that prospective payment should not be substituted for cost reimbursement. But even its proponents conceded that the new system would have to be changed in two important ways: first, to account for the differences in hospital expenditures caused by severity of illness, and second, to put tighter limits on utilization.

Severity of illness was already a subject of HCFA research when the Prospective Payment System was installed in 1983 because early studies suggested that severity of illness was frequently a more accurate predictor of hospital expenditures than DRG classification. If DRG classification was to be made the basis of reimbursement, equity required that HCFA find some way of modifying the classification scheme to give severity of illness appropriate recognition. The main obstacle has been to find a reliable. efficient, and inexpensive means of determining severity, and research on that point continues. If a means is found and incorporated into the reimbursement system, those concerned to protect access to critical care services will be relieved.

Controlling utilization will require something more. The Prospective Payment System discourages two forms of inappropriate utilization, but it creates the possibility of two forms of abuse.

The hospital is discouraged from keeping patients longer than necessary and from providing more or more expensive services than necessary by payments that are fixed at levels designed to reflect the length of stay and the services required to treat the patient's condition appropriately. Given the constraints of the system, its critics worry more about underutilization - hospitals denying or skimping on needed services and discharging patients too early - than about overutilization. The system's defenders point out that physicians, not hospitals, decide which services patients are to receive and when they are to be discharged, and that hospitals and physicians are subject to heavy penalties if underutilization leads to malpractice suits, successful or

One abuse the system must guard against is unnecessary admissions. Under the prospective payment system, as under its predecessor, hospitals are only paid when services are provided, and now they have a powerful incentive to admit patients whose treatment requires less care and thus lower expenditures than the DRG payment.

Here again, the primary protection lies in the division of function: it is the physician, not the hospital, who admits patients, and physician behavior is monitored to prevent reimbursement to hospitals for services to patients admitted unnecessarily. The watchdog is the Professional Review Organization (PRO), successor to the largely ineffective PSROs. The PROs are developing for each DRG a list of indications for admission. If a patient is admitted in the absence of those indications, and the admission cannot be justified on other grounds, reimbursement for the services provided is denied.

The other potential abuse results from the inappropriate classification of patients. Given rules that reward putting patients into some DRGs more than others, it is only reasonable to expect that some hospitals will succumb to the temptation to classify patients inappropriately. Careful PRO review is intended to prevent this abuse.

The promise and early success of Medicare's Prospective Payment System inspired other third-party payors in the public sector (e.g., state Medicaid programs) to consider using the system as the basis of their own reimbursement schemes, but most held back, waiting to see whether the new system would work, how it would be phased in, and whether its acknowledged imperfections would be corrected.

In the private sector, meanwhile, employers and insurers were developing their own strategies to control the increase in health care expenditures. During the 1970s and early 1980s, attention focused on the prevention of known abuses. Unnecessary surgery was checked with second opinion programs that denied reimbursement for elective surgery performed in the absence of a second opinion concurring in the need for the procedure. Unnecessary hospitalization for elective surgery was discouraged by the requirement that surgery be performed on an ambulatory basis where possible or by reimbursement schemes that paid physicians more for outpatient surgery than for the same procedure performed on an inpatient basis. Unnecessary admissions were reduced by requirements for prior authorization from the employer or the insurer. Length of stay was reduced by denying reimbursement for days in the hospital prior to the performance of procedures or the initiation of therapy; Friday admissions for Monday surgery have been reduced dramatically, and admissions for tests that could be performed on an outpatient basis are fast disappearing.

Next to the complexities of the Prospective Payment System, devices like these appear rudimentary, but their effect has been remarkable. At the beginning of 1983, for example, Blue Cross and Blue Shield of North Carolina began requiring prior approval of all but emergency admissions for a large employer in Western North Carolina. Despite the fact that Blue Cross approved every requested admission, hospital utilization in the 2,500-member group dropped 37% in a single year.

The implementation of these controls has been slow because it takes time to develop the appropriate mechanisms, to persuade employers to agree to them, and to implement them. Even so, hospital utilization by people enrolled in plans administered by Blue Cross and Blue Shield of North Carolina declined 23% between 1982 and 1984, and the decline is continuing. Most observers expect further reductions in North Carolina in the next few years.

The experience to date suggests:

1. The protest of physicians and hospitals to the contrary notwithstanding, there was a lot of fat in the system. For all the expenditures that have been avoided, for all the savings achieved, there has been no evidence that reductions in utilization have resulted in widespread harm to patients.

2. Even though their strategies differ, public and private sector efforts to reduce unnecessary hospitalization are succeeding and they are mutually reinforcing. Physicians and hospitals are gradually learning more efficient, less expensive ways to provide care.

3. Regulatory efforts to prevent unnecessary hospitalization will expand and intensify, and substantial further reductions in hospital utilization will be achieved in the

next few years.

Even so, the most dramatic reductions over the next decade are likely to come from a different quarter: competition.

When you mention "competition" to physicians and hospital administrators, they naturally think of competition among physicians, among hospitals, or between physicians and hospitals, as for patients requiring radiological tests or ambulatory surgery. That competition is a powerful force in the health care marketplace, and it will continue. But the competition that may soon play a more important role is competition among insurance plans, for employers and employees are going to be offered a wider range of choices than ever before.

The choices will differ in several important respects: in the types and volumes of services provided; in the freedom granted patients to choose their physicians and hospitals; and in the premiums that employers and employees are required to pay. And the plans will be modified over time, as their designers try to find the right combination of benefits and prices for the markets in which they must compete.

Insurance plans differ widely in their organization and operation, and new variants are evolving so rapidly that it would be foolish to attempt a complete typology. But most plans can be put into one of three categories:

1. Indemnity insurance arrangements. These are the traditional plans. They typically offer the enrollee freedom of choice among providers, but they also include deductible and co-payment requirements that make them more expensive than the alternatives.

2. Preferred provider organizations. These offer lower premiums than indemnity insurance plans, in return for the enrollee's agreement to use designated ("preferred") providers. The more expensive providers are typically excluded.

3. Prepaid plans. These plans differ from both indemnity insurance and preferred provider arrangements in that providers are prepaid: the amounts that they will receive are determined in advance by multiplying the amount allowed for the care of each patient by the number of patients for whom the provider accepts responsibility. In some prepaid plans (e.g., the Personal Care Plan offered by North Carolina Blue Cross and Blue Shield), only the primary care physician is prepaid; consulting physicians and hospitals are paid the traditional fee for service. In other plans, all physicians are prepaid, and hospitals are not. In still others, physicians and hospitals are all prepaid.

One term commonly used to describe prepaid plans is "capitated": providers are paid on a "per head" basis for the enrollees for whom they accept responsibility, rather than on a per service or per case basis. If their patients require fewer or less expensive service than anticipated,

providers will typically share in the savings. If their patients consume more or more expensive services than expected, providers are obliged to share in the loss.

In fully capitated plans, no provider has a incentive to provide care that is not essential, and the expectation is that they will all attend their own interests and provide efficient, economical health care. To make sure that they do, most plans examine carefully the utilization patterns of participating providers, employing automated information systems to analyze utilization data. Physicians found to deviate substantially — in either direction — are made the subject of peer review, for prepaid plans cannot afford the expenses that result from overutilization or the harm to patients that could result from underutilization. In this way, and through the use of their buying power to extract discounts from hospitals, plans hold their expenses and premiums down. Whatever their effects on total health care expenditures, there can be no question that prepaid plans have reduced the rate of increase in expenditures for enrollees, chiefly by reducing hospital admissions.

For employers, governments, and other third-party purchasers of health care services, the appeal of prepaid plans is obvious. Companies that formerly offered their employees only the traditional indemnity arrangement now offer a wide range of alternatives, and governments are making participation in prepaid plans possible and attractive for Medicare and Medicaid beneficiaries.

In cities like Minneapolis and San Francisco, prepaid plans already command large shares of the health insurance market, and they are growing quickly in cities from Boston to San Diego. In rural areas, prepaid plans will develop more slowly, but they are coming, not least because companies capable of creating them are evolving rapidly. Insurers like Massachusetts Blue Cross and Blue Shield have developed both staff model health maintenance organizations and independent practice associations, employing physicians full time and under contract to serve enrollees in a variety of prepaid plans. Hospital service corporations like Humana and the Hospital Corporation of America are developing insurance divisions that will allow them to market a full range of coverages, from traditional indemnity to fully capitated prepaid plans. Multi-institutional hospital systems like the Voluntary Hospitals of America are entering into joint ventures with insurers like Aetna. Physician groups are banding together to negotiate working agreements with hospitals and insurance companies to offer prepaid plans of their own. And established operators of prepaid plans, from Kaiser in the west to the Harvard Community Health Plan in New England, are expanding rapidly. In some urban areas, employers now offer their employees a choice of ten or twenty plans, in addition to traditional coverage.

What do these changes portend for critical care?

Not much, some argue. After all, employers, insurers, governments and other third-party payers are successfully reducing the rate at which health care expenditures increase simply by eliminating unnecessary hospitalization, and the data on utilization demonstrate that much more can be achieved without even questioning the services provided to people who plainly require hospitalization. Perhaps critical care will escape unscathed.

It will not. Critical care will be scrutinized and squeezed over the next ten years because:

- 1. Logic dictates it. If the examination of admissions can be made to yield substantial savings, how much more could be saved by scrutinizing services to patients admitted?
- 2. As Medicare's Prospective Payment System is fully phased in, the special allowances for reimbursement of capital costs and the indirect costs of medical education will be reduced or eliminated, and hospitals' historic expenditures will no longer enter the calculation of reimbursement rates. The 1% per year increase in DRG payments to compensate hospitals for the increasing intensity of their services has already been cut to .25% and may be abolished. As these factors have served to benefit and protect hospitals that provide much of the nation's critical care, their reduction or elimination will almost certainly result in internal reviews of critical care policies and utilization.
- 3. Our ability to collect and manipulate data has now expanded to the point where evaluation of the services provided to hospitalized patients is feasible. Acute care hospitals across the country are now required to supply detailed information about each patient and the services provided with claims for reimbursement, and third-party payers are quickly developing the software required to analyze the data. As the required data include information about critical care services, it is only reasonable to expect questions in that area.
- 4. The aging of our population and our expanding capacity to help those in need suggest that critical care services will continue to expand and that expenditures for critical care services will consume a growing share of expenditures for health care. Controlling expenditures for critical care will soon appear an essential element in any strategy designed to reduce the rate at which health care expenditures increase.
- 5. The aging of our population is changing the ratio of those working to those dependent on others. If we continue to retire people at 62 and 65, the ratio will soon reach one to one.
- 6. Recent analyses of critical care services disclose substantial disagreements about their efficacy and appropriate use. With knowledgeable observers asking whether services are provided to patients who don't need them, patients who could be served equally well in less expensive settings, and patients who are beyond help, third-party payers are certain to ask what portion of expenditures for critical care services are wasted.
- 7. Competition among prepaid plans will intensify, and price will play a growing role. Simultaneously, the more successful plans will grow, and their buying power with physicians and hospitals will increase. Physicians and hospitals will be expected to discount their prices in an environment where they will find it increasingly difficult to pass the cost of the discounts to other payers. They will have to find less expensive ways of meeting their obligations, and reducing the use of critical care services will seem an obvious and attractive alternative.

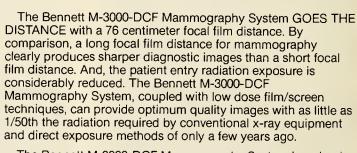
Those concerned to protect critical care services sometimes take comfort from this nation's refusal to accept the rationing of health care service. They cite policies adopted by England's National Health Service and argue that "It can't happen here."

They miss the point. Health care services in this country are rationed by the willingness of payers to pay for them. For the last twenty years that principle has been obscured both by the operation of a health insurance system committed to reimbursing providers' expenses and expenditures and by the extension of insurance protection (through Medicare and Medicaid) to people previously without thirdparty coverage. The supply of health care providers and services has grown much faster than the population, and the share of the gross national product devoted to health care has doubled.

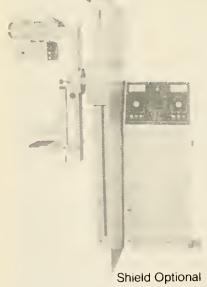
Now the pendulum is swinging the other way. Payers are increasingly determined to reduce the rate at which health care expenditures increase, and now they have found

the tools they need: devices like the Prospective Payment System and competing prepaid plans, which limit the dollars spent for health care without rationing services. The supply of health care providers and services will continue to grow rapidly, but the supply of dollars to pay for them will not. Competition for those dollars will grow more intense and less rewarding for all providers, including those involved in critical care. New critical care services will be developed, but the utilization of critical care will be limited by policies designed to prevent its use except where appropriate, essential and productive. These policies will not be developed by politicians or enforced by bureaucrats. They will be developed and enforced by physicians and hospitals who have been enlisted, however unwillingly, in the effort to curb the increase in health care expendi-

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## Rats, Rabbits and Reproduction

John W. Everett, Ph.D. and James F. Gifford, Jr., Ph.D.

• From the Editor: When I came to Duke in January 1947, I attended a seminar organized by Dr. Joseph Markee, the Professor of Anatomy. For the first time I was introduced to the budding infant neuroendocrinology. I was intrigued by the evidence that a hormone produced by the brain travelled by a specialized venous portal system to regulate the output of the anterior pituitary gland. I learned for the first time of the role of the nervous system linking coitus to ovulation in some animals and of Dr. Everett's early studies on the influence of light and ovarian hormones in regulating the female reproductive cycle.

At my urging Everett and Gifford have written an account of Duke's role in the early history of neuroendocrinology. You need to spend some energy to appreciate the finer points of this paper. No one has found a

way to broaden one's horizon without effort.

E NDOCRINOLOGY, or the study of internal secretions and the ductless glands, appeared as a specialized field for scientific research in the latter half of the nineteenth century in Europe. In the early decades of the twentieth century both clinical and basic science research activities emerged in the United States, where the first professional society of endocrinologists was established in 1917. In Europe early research activity was concentrated in established scientific centers but in America, in part because endocrinology was a field of interest rather than a discipline with specific methodologies, significant lines of investigation developed in a variety of laboratory and university settings. The Department of Anatomy at Duke University School of Medicine became one of these.

By the mid-1930s reproductive endocrinology was an active field of research. The anterior pituitary gland had been well established as a controller of body growth, the thyroid gland, the adrenal cortex, milk secretion, and the gonads in their dual role of producing germ cells and the sex hormones. Several laboratories were attempting to isolate and purify the secretions of the anterior pituitary. The gonadal steroids (estradiol, progesterone, testosterone) were chemically isolated and commercially available by the late 1930s. Scientists generally accepted the "pushpull" hypothesis of Moore and Price to explain pituitarygonadal function in the female reproductive cycle, picturing the alternate suppression and release of gonadotropins as the gonadal steroids increased and diminished. The corpus luteum through its hormone, progesterone, was known to suppress ovulation while preparing the uterus for pregnancy. The nervous system generally was thought not to be important in mammalian endocrinology, although there was some suggestive evidence for a neural role in basic gonadal support. Neural participation in the coitallyinduced ovulation in rabbits, cats and ferrets, and in the induction of pseudopregnancy in rats by genital stimulation, were considered to be special cases. For study of the female cycle in rats and some other mammals the vaginal smear technique was a generally accepted procedure.

During the following 30 years, several anatomists at Duke University made numerous major contributions to reproductive endocrinology that were fundamental to a developing understanding of neural control of the pituitary gland. The first phase of that research, from 1935 to the mid-1940s, involved the actions of estrogen, progesterone and prolactin in the female cycle of rats, particularly in the control of ovulation. The importance of controlled illumination in animal studies was demonstrated. During the second phase, from 1945 to 1953, intensive studies compared in several ways the mechanisms for reflex ovulation in rabbits and the spontaneous process in rats. Included were electrical stimulation of the rabbit hypothalamus, injection of epinephrine into the hypothalamo-pituitary system, and demonstration that antiadrenergic and anticholinergic drugs can block the ovulatory release of gonadotropins in both rabbits and rats. Control by a 24-hour physiological clock was shown in rats. In the third phase, developments from 1953 to 1965 included an electrochemical method for stimulating the rat brain, mapping brain areas where stimulation results in ovulation and demonstration that anterior pituitaries transplanted away from the brain secrete prolactin abundantly while losing other powers. Restoration of fertility when grafts were later replaced near the hypothalamus confirmed the importance of vascular linkage with that part of the brain.

#### Phase I. Rats With Interesting Defects, 1935-1945

The Duke University School of Medicine, opening in 1930, resembled the Johns Hopkins University School of Medicine, from which most of the original Duke faculty

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was drawn, both in its emphasis on research and in the structure of its medical curriculum. Teaching was scheduled on a "block" system, each department having major teaching responsibility during certain calendar months with other times free for investigation. Anatomy was taught during the first semester of each year, with the second semester and summer offering faculty generous amounts of time for research.

Three members of the Department of Anatomy at Duke in the 1930s had research backgrounds in embryology. The chairman, Francis H. Swett, was an experimental embryologist whose speciality was the early development of limbs in amphibians. His protege, Henry Hollinshead, also was interested in limb development but in addition studied the autonomic nervous system. John W. Everett, who like Swett completed his doctoral studies in zoology at Yale, focused his dissertation on the functions of the placental membranes in albino rats. Intending to continue this work, Everett brought with him in 1932 a few rats of the mixed strain he maintained at Yale, since commercial sources of experimental animals did not yet exist.

A small experimental colony was derived from these rats by brother-sister pairing.6 Within a few generations of inbreeding, certain peculiarities appeared which led Everett eventually to become an endocrinologist. Many of the females were infertile. To avoid that, it was necessary to begin breeding before they were 100 days old and to return fertile females to stud immediately after weaning. Many virgin females, soon after reaching the age of four months, presented persistent vaginal estrus (cornification signifying continuing production of estrogen associated with polycystic ovaries). Infertility of breeders was greater in winter than in summer, suggesting some relation to daily exposure to light (importance of controlled lighting for rat colonies was not yet recognized). In an attempt to reverse the wintertime decline in fertility, Everett kept the lights on in the colony room for nine days in December 1938. Immediately, almost all of the cycling rats developed persistent estrus. In subsequent experiments, exposure of rats to winter-like 9-hour days resulted in progressively longer periods of diestrus in young rats, while persistent estrus in older ones was often replaced by cycles. Exposure to summer-like 14-hour days reversed these effects, restoring regular short cycles in young rats and persistent estrus in older ones. Thereafter the colony room lights were regulated to give 14 hours of light and 10 hours of darkness daily. The seasonal effects disap-

The frequent spontaneous occurrence of persistent estrus in middle-aged rats offered a unique opportunity to study factors regulating the estrous cycle, especially in view of the fact that cycling could be restored by simply changing the lighting schedule. Furthermore, corpora lutea could be induced by injecting pituitary extracts. Possible roles of estrogen and progesterone were next examined. Supplementing the rats' own estrogen by giving estradiol benzoate failed repeatedly to induce ovulation and luteinization, but success came with certain progesterone treatments. Progesterone was already known to suppress ovulatory cycles in rats when injected daily with 1.5 mg or more. This was confirmed; the same treatment of per-

sistent-estrous rats induced anestrus. Subsequent experiments demonstrated that progesterone may also act positively to facilitate the action of estrogen in promoting ovulation. The positive or negative effect depended on the amount administered and the times of treatment within the estrous cycle.

A sequel to this was based on reports from other laboratories that prolactin is luteotropic in rats, sustaining progesterone secretion by the corpora lutea. Everett determined that once an initial set of corpora lutea had been induced in persistent-estrous rats, daily injection of small amounts of prolactin could sustain a series of estrous cycles, supposedly by causing low-level secretion of progesterone. It thus appeared that during the normal short cycle the corpora lutea may not be totally inactive as commonly thought.

At this point, critical comparisons seemed essential between rats of the defective stock (identified as the DA strain) and normal rats under identical conditions. An inbred colony of vigorous normal rats from the Osborne-Mendel (O-M) strain was established for this purpose in 1940. In addition to their excellent breeding performance these animals showed other important differences from DA rats. Tested by the occurrence of constant vaginal estrus when exposed to continuous lighting, the two strains differed markedly in rapidity of response, the DA rats responding much more rapidly than the O-M rats, with hybrids intermediate. A combined influence of age and genetic background was demonstrated in both spontaneous and light-induced prolonged estrus.

Experience with the two strains under the 14h:10h light:dark regimen disclosed that cycling females tended to have regular cycle lengths of either four or five days, the longer cycle having an extra day of diestrus. Since evidence indicated that estrogen secretion rises in late diestrus, it seemed possible that progesterone administration on the day before proestrus might enhance the action of estrogen so as to advance the time of ovulation. When this proved to be true for rats having regular 5-day cycles, the positive role of progesterone in prompting gonadotropin secretion was confirmed.

#### Phase II: Rats and Rabbits, 1945-1953

In the early 1940s both teaching and research in the Department of Anatomy at Duke were disrupted by the turmoil of WWII. The medical curriculum was accelerated, with a new class admitted to the School of Medicine every nine months. Perhaps in part because of increased administrative responsibilities, Dr. Swett died suddenly in February 1943. His successor as chairman was Joseph E. Markee, an authority on primate uterine physiology. While working at Stanford with Joseph Hinsey, Markee had studied the role of the nervous system in the coital reflex that stimulates the rabbit anterior pituitary to secret gonadotropin for ovulation. After various failures to block the effect by surgical interruption of autonomic pathways that might reach the pituitary gland, Hinsey and Markee had suggested that "pathways from the hypothalamus must activate the posterior lobe . . . which in turn may exert an effect on the anterior lobe by humoral transmission."

Stanford, Charles H. Sawyer, whose interest in the neural regulation of pituitary secretion focused on the ontogeny of the enzyme cholinesterase in salamander embryos, with emphasis on correlations with developing motility. Together with Everett and Hollinshead these men formed a new research team whose overlapping interests produced a series of fundamental contributions to the area of reproductive endocrinology later to be termed neuroendocrinology.

The initial collaboration between Sawyer and Everett was in a series of studies of the influence of hormones on serum cholinesterase. The results disclosed that estrogen increases the serum concentration of both specific and non-specific cholinesterase in persistent-estrous rats, in late pregnancy, and in pseudopregnant rats treated with estrogen. Evidence for the liver as the source of the enzymes included their abrupt reduction after hepatectomy and their gradual reappearance as the liver regenerated.

Meanwhile, Sawyer joined Markee and Hollinshead in studying the ovulation reflex of rabbits. Following a series of experiments in which electrical stimulation was applied selectively to the vagus nerve, the anterior pituitary gland or the hypothalamus, they concluded that the hypothalamus controls the anterior pituitary through a type of neurohumoral linkage, a conclusion supported by other investigators working independently. They then attempted with some success to induce ovulation by injecting epinephrine into the hypothalamo-pituitary system and examined the influence of certain newly developed adrenolytic drugs on the coital reflex. They discovered that one of these, Dibenamine, and a related drug blocked ovulation if injected intravenously within a minute after coitus. In addition, the rapid injection of atropine sulphate similarly blocked the reflex. Critical examination indicated both a cholinergic and an adrenergic link in the ovulation reflex, operating in that order. Further studies based on these results tested the influence of other drugs on pituitary activation. The effects of the adrenergic agents eventually led to extensive investigations in many laboratories showing that catecholamines exert important controls on pituitary secretions, acting both in the gland and in the brain stem.

Sawyer and Everett tested the possibility that Dibenamine and atropine might block ovulation in rats. When results showed that estrogen-induced ovulation in rats could be blocked by the same agents that interrupted the coital reflex in rabbits, this implied the existence of a similar cholinergic-adrenergic linkage in the two species.

The next question was whether the drugs would block spontaneous ovulation if injections were appropriately timed with respect to time of day and stage of cycle. The results were positive, demonstrating both cholinergic and adrenergic factors in some acute event that is necessary for cyclic ovulation and analogous with the reflex process in rabbits. Previously, spontaneous ovulation had been viewed as the culmination of gradually accelerating gonadotropin secretion. Nembutal and other barbiturates were also effective blockers in rats. There was a 2-hour critical period on the proestrus afternoon when the various blocking agents must act to be successful. Studies with Nembutal disclosed a 24-hour periodicity in the "LH-release"

apparatus" of rats (see figure 1). Knowledge of this periodicity, together with reports from other laboratories that large lesions of the rostral hypothalamus would cause failure of ovulation in guinea pigs and rats, led Everett and Sawyer to propose that the rostral hypothalamus contains a physiological clock responsible for the rhythmicity. The results confirmed the impression gained from the 24-hour advancement of ovulation by progesterone treatment (see phase 1). The clock in the brain of rats and certain other species signals the pituitary to release luteinizing hormone (LH) at times governed by the rhythms of the day-night cycle.

## Phase III. The Rat Model: Spontaneous Ovulation and the Corpus Luteum

The early 1950s were a period of transition. Markee's interest in reproductive physiology diminished as he became increasingly concerned with audiovisual methods of teaching. Sawyer moved to UCLA where he was destined to pursue an illustrious career in neuroendocrinology. Hollinshead had left to become Anatomist at the Mayo Clinic. From 1953 onward most of the endocrine research in the Duke anatomy department centered in Everett's laboratory. These investigations concerned the neural controls for secretion both of LH in timing ovulation and of prolactin in the post ovulatory maintenance of the corpora lutea.

The two-hour "critical period" on the proestrus afternoon was explored by giving atropine sulphate at different times and by parallel experiments with rapid hypophysectomy at similar times. Measured by the declining effectiveness of either procedure for blocking ovulation, the estimated time of release of enough LH for full ovulation was about 30 minutes. There was indirect evidence that the normal surge lasts much longer (as modern assays have proven).

The studies with Nembutal led unexpectedly to the first clear distinction between the controls for ovulation and those producing pseudopregnancy, the latter process being not a simple reflex but a functional change in the hypothalamus persisting for many days. When mating took place during a cycle in which ovulation was blocked by Nembutal, pseudopregnancy began about a week later when corpora lutea had formed from a new set of follicles at the next estrus. The coital stimulus had been "remembered," so to speak, to initiate the typical two-week period of corpus luteum secretion.

Other evidence differentiating the neural controls for ovulation and for corpus luteum maintenance came from experiments in which the pituitaries were transplanted. Searching the literature pertaining to the luteal phase of the cycle, Everett came upon a puzzling experiment reported from Sweden in 1937 by Westman and Jacobsohn. They had cut the pituitary stalk of rats in estrus, placed a metal foil barrier between the brain and pituitary, and several hours *later* had stimulated the uterine cervix. The rats became pseudopregnant. But how could the stimulus have reached the pituitary? One control was missing—that of simply disconnecting the gland from the brain. To test this, Everett felt that if the anterior pituitary were transplanted to a site distant from the hypothalamus, that

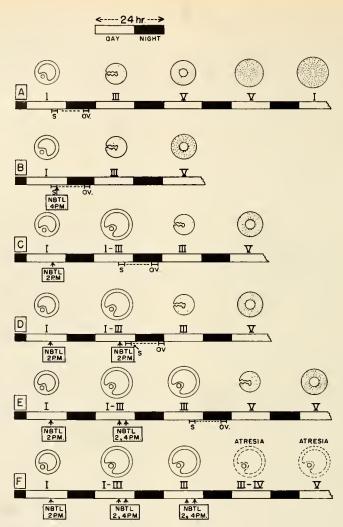


Figure 1. Demonstration of 24-hour periodicity in the luteinizing hormone-release apparatus of female rats (4-day cycle, controlled lighting: 14 hours per day). Schematic representations of the normal cycle (A) and of characteristic results of different regimes of Nembutal treatment (B-F). Vaginal stages indicated by Roman numerals over each time scale; symbols above these show the corresponding follicle and corpus luteum stages. The device marked S defines the "critical period," the time limits of pituitary activation as experimentally determined. OV indicates normal oxulation time in A and estimated oxulation time elsewhere. NBTL indicates intraperitoneal injection of Nembutal. (From Everett JW, Sawyer CH. Endocrinology 1950;47:200.)

in itself would constitute a suitable control. Parapharyngeal hypophysectomy was performed on the day of estrus when new corpora lutea were forming, and the anterior lobe was immediately transferred to a kidney capsule. The result was predictable; pseudopregnancy in every case. In long-term experiments, the corpora lutea were functionally maintained for months as long as the graft remained on the kidney. Because the principal luteotropic agent in rats is prolactin it was apparent that prolactin secretion was enhanced, the first evidence of an inhibitory effect of the brain on pituitary secretion. Secretion of other trophic hormones was largely lost, as indicated by regression of

ovarian follicles, thyroids and the adrenal cortex. There was no histologically demonstrable trace of pituitary tissue in the original site in crucial cases.

It was logical at that point to inquire whether a transplanted pituitary, having lost ability to maintain normal estrous cycles and ovulation, could regain that competence if retransplanted close to the hypothalamus. Geoffrey Harris in England had shown the remarkable ability of the pituitary portal vessels to regenerate, and Harris and Jacobsohn had shown that pituitary transplants placed at once under the hypothalamus after hypophysectomy rapidly became functional. At Duke the re-transplantation

experiment was carried out by Miroslava Nikitovitch-Winer in research for her Ph.D. dissertation (1957). After the transplanted gland had first been on the kidney for three to four weeks, she replaced it close to the median eminence, using the delicate transtemporal approach to the basal hypothalamus devised by Harris. The result was that estrous cycles returned in many cases, sometimes within a few days. There also was significant restoration of the thyroids and adrenals. Several rats became pregnant when mated. There were correlated changes in the cytology of the anterior lobe. Grafts on the kidney lost the prominent basophilic gonadotrophs and thyrotrophs, which promptly reappeared in the retransplanted glands, in spite of the double insult from the two operations. This dramatically confirmed the importance of blood-borne agents from the hypothalamus in control of anterior pituitary functions.

Although the essential neurohumoral influence of the hypothalamus on the pituitary function and the blockage of rat ovulation by drugs strongly implied that the crucial signal to the rat pituitary for ovulation comes from the brain, until 1957 there was no direct evidence that experimental brain stimulation could supply that signal. Independent studies by Critchlow, to a student of Sawyer at UCLA, and by Joseph Bunn and Everett at Duke were first to show this. The Duke investigators used as subjects rats that were in persistent estrus induced by continuous light. Electrodes were stereotaxically implanted in advance of stimulation, which was later carried out without anesthesia. In 10 rats the electrodes were in the medial amygdala, a site chosen because Norman Shealy and Talmage Peele had reported that female cats could be made to ovulate by electrical stimulation of that region.11 On the day after stimulation, tubal ova were present in five rats and the others showed histological evidence of ovarian activation. By contrast, the subjects in Critchlow's experiments were proestrous rats stimulated under Nembutal anesthesia during the critical period. His effective stimulation sites were chiefly in the medial basal hypothalamus close to the median eminence and origin of the pituitary stalk.

Attempting to repeat Critchlow's work, Everett, R. L. Riley, J. R. Harp and H. M. Radford explored the hypothalamus with a variety of electrode sites for stimulation under Nembutal anesthesia. The medial preoptic area was a much more reliable site for stimulation than the median eminence, requiring far less exact electrode placement. After much trial and error with different electrical pulse characteristics came realization that even brief passage of anodic direct current could induce ovulation, provided that equivalent amounts of electricity were delivered. The common factor with pulses or direct current was the electrolytic deposition of iron from the stainless steel electrodes. On the other hand, there was no such effect from electrolytic lesions made with platinum electrodes or with implanted cylinders of compressed powdered glass. The lesion produced with an iron alloy electrode apparently formed an irritative focus that continued to act long after the passage of electrical current. Thus was discovered the electrochemical method of stimulating the rat brain to induce pituitary secretion, a method that became a basic tool in

neuroendocrine research.

From the extensive exploratory experiments leading to its discovery, both the location and strength of an electrochemical stimulus determined the results. The range of stimulation sites effective for ovulation indicated a diffuse preoptic-tuberal neuronal system in the medial preoptic area, converging sharply near the median eminence. Moreover, the amount of iron deposited and the extent of the resulting lesion determined the rate of LH released by the pituitary. Only stimuli involving the entire medial preoptic area could achieve release of an ovulation quota of LH in 30 minutes.

#### Concluding Remarks

By the mid-1960s neuroendocrinology had emerged as a vigorous discipline in its own right, concerned with the role of the central nervous system in selectively controlling secretions of all parts of the pituitary complex, with feedback action of peripheral hormones on the brain and pituitary, with the influence of environmental factors and with behavioral correlates. 12 The common occurrence of neurosecretion throughout the animal kingdom had gained general acceptance.13 Many scientists were by then at work in the field. Although much had been learned, refinements of methods were urgently needed. The availability of sensitive assay methods to measure minute amounts of hormones in the blood stream was several years in the future. The race among research groups to isolate, purify and chemically identify the hypothalamic "releasing factors" was in full swing, but would not reach its dramatic climax for another decade.14

#### Acknowledgment

Dr. Gifford acknowledges the assistance of the Josiah C. Trent Foundation.

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## Fee-for-Service vs Alternative Delivery Systems

Eugene W. Linfors, M.D., editor

 The question for April is: Will traditional fee-for-service practice survive pressure from alternative delivery systems? Should it?

### From Dr. Larry M. Crane, a radiologist from Durham.

To even ask whether traditional fee-for-service medical practice will or should survive is to also state that it is in trouble. The answer to the question requires examining the reasons for trouble, possible solutions offered by "alternate" forms of health care delivery, potential difficulties with these alternate methods, and any positive aspects of fee for service.

Physicians tend to think of fee for service in terms of personal freedom, both for themselves and for their patients. As independent deliverers of health care, no one (except the courts and certain hospital committees) looks over their shoulder to dictate standards of care, style of practice, fees, or billing methods. While this traditional method allows for great variation in style, it also allows for great variation in both quality and cost.

Alternative systems offered potentially lower costs or, with some systems, greater benefits at the same cost. The source of those cost savings was alluded to be an emphasis on preventive care and "health maintenance" (a public relations dream term). Lured by this apparent health nirvana, a number of patients began actively choosing alternative health systems. It was not until the largest single purchaser of health care, the government, began to make its opinion felt that alternative health delivery systems were seriously considered by many, however. With the assistance of government grants and official blessing, the alphabet soup of HMOs, PPOs, and IPAs was served on a wider scale. The main impetus to development of alternative delivery systems, however, was pressure from the business community. During times of recession, business was forced to look at all its expenses, and health benefit costs were not excepted. Since businesses are the largest purchasers of private health insurance, their opinion that alternative health care delivery systems would cost significantly less than the traditional indemnity insurance (the main funder of fee for service) dictated their exploration of those concepts.

Studies have shown the only real cost savings in these various systems is in the decision not to hospitalize or to delay hospitalization until all outpatient testing and treatment modalities are finished. Most other cost savings are

related to denial or delay of medical care. These savings are achieved through various methods, including gate-keepers, computer screens, appeals to the gatekeeper's wallet, and limiting access to specialty care. This has led to questions of decreased quality of care under the alternative systems. Proponents of these systems answer by pointing out the lack of "studies" showing any quality differences, knowing that there are few accurate ways to really measure the quality of health care. Questions of quality may be moot, however, since businesses and individuals (and, indeed, our own profession) had difficulty accurately gauging quality under the fee-for-service system, either.

Despite the reservations of the majority of practicing physicians about the quality and style of alternative health care systems, many patients will continue to choose them merely on a financial basis. Those who have been priced out of fee-for-service care will at least still have access to medical care, despite limitations of choice, questions of quality, and some impersonality of delivery. Others may desire the cost savings more than the perceived drawbacks (if they actually recognize any). The fee-for-service system will still offer the Cadillac of care by preserving freedom of choice, a one-on-one physician-patient relationship, and probably better quality through individualized care, albeit at possibly higher prices. Politicians, businesses, and some individuals will refuse to pay this higher price, leading to a multi-tiered health care system, despite our efforts at obtaining the highest quality for all.

Yes, I think the fee for service system will survive, because most of the public wants their physician to be their advocate and not the saviour of some business or political enterprise. Nonetheless, advocates of fee-for-service medicine will need to alter their practices to recognize public concerns over cost and availability. The savings of outpatient medicine where possible can not be savings of outpatient medicine where possible can not be ignored. In some areas, this may mean becoming more involved in physician control of alternative delivery systems, so that quality controls remain in medical and not business hands. My personal feeling is that the best of the traditional and alternative systems will be a blending of the two into a Managed Indemnity Plan (a fee-for-service indemnity insurance with physician-directed quality controls on utilization and admissions). Despite their objec-

tions, physicians will have to recognize public opinion and participate in some alternative systems (at least those where they will not feel ethically or legally restricted). It may be necessary to form your own physician HMO or PPO to offer a competitive product in which such restrictions are not present.

Some say the first war of competing health care systems will be over the pricing of the "product." The second conflict will be over quality, if there are any quality products left to compete after the price war is over.

## From Dr. William W. Fore, an endocrinologist from Greenville

Yes, the fee-for-service system will, and should survive. There are many reasons for this. Co-payment and more "uncovered" medical services are a routine part of current health insurance coverage. The organizational format of newer alternative delivery systems is compensating physicians on a fee-for-service and not a salaried basis. Dr. Alvin Tarlov projects that by the year 2000 only 150,000 of 650,000 physicians in this country will be working in a prepaid care system. This will leave the majority of physicians in a fee-for-service system. Many physicians will participate in part or compete with prepaid care. There is no question that the number of physicians working on a salaried basis will increase, but this will not be of sufficient number to totally replace the current fee system.

DRGs, prepaid care, managed care, preadmission certification, denial of coverage, second-opinion surgery, and all of the recommended "cost-saving devices" now being applied to our health care system will only slow, not stop, the increase of medical cost. These cost-saving devices do not address the three largest factors that increase our medical care costs. First, 50 to 60% of hospital costs are to pay personnel salaries, and these will rise with inflation. Second, new and very expensive medical technology is introduced and utilized even before clinical studies showing definite benefit are completed. Third, our population is aging rapidly and requires more medical care each year. Against these forces, the cost of medical care in this country will continue to rise! Unless we as a society decide to deny care to some or provide less care to all, costs will continue to increase greatly.

I fear that budgetary restraints, primarily on the part of government and business, will result in three *unequal* levels of medical care:

- 1. Care of those paid for by government
- 2. Care of those provided by industry
- 3. Care of those able to pay their own expenses

I hope that in this rush for more-for-less that the old, the poor, and the disabled will not be the losers. Realistic planning for this is not receiving the attention given to the more fashionable "cost-saving devices."

## From Dr. John R. Gamble, a general surgeon from Lincolnton

In response to the first part of the question, I believe that fee-for-service will survive but will only serve to firmly entrench a three level health care delivery system in the U. S.

I shall assume that the second part of the question is intended to mean "Should it morally?" Yes, if it will contribute to medical advances that will trickle down to all levels. No, if the medical profession becomes a party to the rationing of good medical care.

### From Dr. Charles L. Garrett, a pathologist from Jacksonville

I am a forensic pathologist engaged in hospital-based practice in an essentially salaried role, and my other income is derived on a fee-for-service basis from the State of North Carolina and its various counties for the performance of medical examiners' examinations and autopsies.

Alternate delivery systems of health care will not particularly impact my practice and due to the restrictive covenants of my contract I would be unable to participate if they did.

## From Dr. Derek Prentice, a family practitioner from Durham

HMOs, IPAs, and PPOs are alternative health delivery systems which have grown up in competition to traditional fee-for-service medicine. It should be noted, however, that they are exactly that - ALTERNATIVE delivery systems. Evidence from across the country shows that they do not replace fee-for-service medicine; only a proportion of the market will adopt these alternative systems. I have chosen to work for a group model HMO in which individuals and employers pay a monthly fee to insure that all medical services for members are provided through the offices and consultants of the HMO. The physicians working for the HMO are a multispecialty group practice, which contracts with the HMO to provide all the medical services for the HMO members. This system requires that a certain volume of patients are enrolled to support the system so that the "healthy members" support the illnesses of the "unhealthy members" at any given time. HMOs are also heavily involved in preventive measures in efforts to keep the patient population healthy and at work. The advantage to the employer is a cheaper rate structure; the advantages to the individual member are no deductibles and a designated site for the rendering of care. The disadvantage to the members is the giving up of free choice of physicians outside the HMO. In areas with large population densities, the "unhealthy members" are supported by the "healthy members," and the HMO's effort to maintain good health practices such as immunizations, exercise programs, weight control programs, and cigarette cessation programs can be more cost-effective. In rural areas with a less dense population, HMOs cannot generate a large enough population to support their activities. Fee-for-service medicine offers a model which will allow patients who wish to control their own health management and referrals to do so. However, where patients wish to work with a health care manager to insure they get the appropriate care, the HMOs have certain advantages.

The HMO that I'm involved with prefers to be only one of a list of options of health plans offered to employees, because we understand that HMOs are not a method of health care that will be appropriate for all. The Kaiser health plan grew from patient demand in the 1940s and continues to grow. The Kaiser health plan is non-profit.

On a personal note, I find working for an HMO an excellent way to allow me to practice good quality, cost-conscious medicine for patients. I can see patients for return visits as frequently as necessary, I can order whatever lab I think appropriate without concern that the patient is responsible for the cost of each service. I am not caught in a situation where patients request to be put in the hospital for particular investigations to be done because their insurance covers inpatient but not outpatient activities. I am not pressured to put patients in the hospital for investigations because insurance companies will only pay 80% of the cost of these on an outpatient basis. I'm encouraged, not penalized, to provide health promotion services.

It has frequently been said in the past that fee-for-service medicine keeps physicians up-to-date and acquainted with the latest techniques, because otherwise patients will choose to go elsewhere. My strong feeling is that the desire to provide top quality service comes from within the physician and is not related to his method of reimbursement. However, the health marketplace these days is so competitive that no system that does not provide cost effective quality medicine will survive whether it be an HMO, an IPA, or a fee-for-service system.

## From Dr. Samuel W. Warburton, a family practitioner from Cary

Will fee-for-service practice survive? The answer is yes, but not in its current form. Alternate delivery systems offer much to both the public and the medical profession. The benefits to patients are continuity of care, reduced out-of-pocket costs, broader benefits and often a primary physician to help the average person through the health care maze. The benefits to the primary care physician are also substantial — patient commitment in the form of enrollment and, therefore, improved continuity of care; better

cash flow, improved information on practice patterns and ways in which to improve cost effectiveness. Many primary physicians report that providing total managed care is professionally satisfying and truly possible, for the first time, in a health maintenance organization. Surveys of satisfaction with care in HMOs demonstrate the public is pleased with the quality of care provided. The benefits to subspecialty physicians are less clear, although the conservative subspecialist will find his/her services more in demand.

The rapid acceptance of various alternate delivery systems in North Carolina is perhaps exemplified by the growth of HealthAmerica. After only 18 months, HealthAmerica is the largest HMO in the state with over 42,000 members cared for by 300 primary physicians. There are almost a dozen HMOs in the state and more developing.

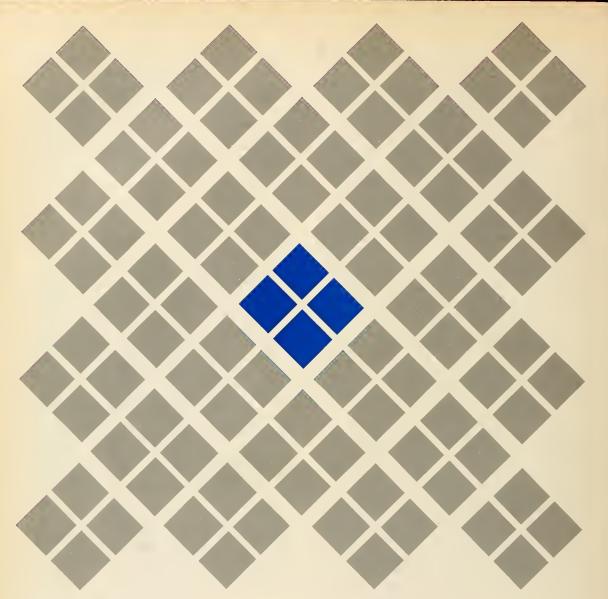
Many private practices will experience a decreasing percentage of fee-for-service care. A number of North Carolina physicians in family practice and pediatrics already report 30% of their practice is prepaid patients. Patients with established personal physicians repeatedly demonstrate that the personal financial cost of fee-for-service care is more than they want to bear and patients are switching physicians in the process of changing health coverage.

Fee for service will survive because alternate delivery systems are not for everyone. Systems of care limit the traditional freedom of the patient and may modify the traditional behavior of the physician. Alternate delivery systems, especially HMOs, provide significant organization to the delivery of health care that is lacking in fee for service. The managed system provides care, facilitates care and controls resource allocation to assure appropriate care. Thus the 25-year-old who is risk factor free but wants a yearly EKG may find it denied in the HMO and opt for more traditional indemnity insurance and pay the higher cost for this freedom.

Fee for service will continue to exist. For some physicians, it may be an exclusive method of practice. Most physicians, however, will participate in alternate delivery systems. The question then becomes how should a physician evaluate participating in an HMO? Perhaps a future forum will address this issue.

#### • EDITOR'S NOTE:

Once again I thank our respondents. This time I asked them to look into a crystal ball and see the future. I am pleased they took a crack at it! It will be very interesting in the next few years to watch how government, industry and consumers vote for their favorite health care delivery system. Keeping health care affordable must be one of our most important goals. However it would be a shame to have the entire system based on what was offered by the lowest bidder.



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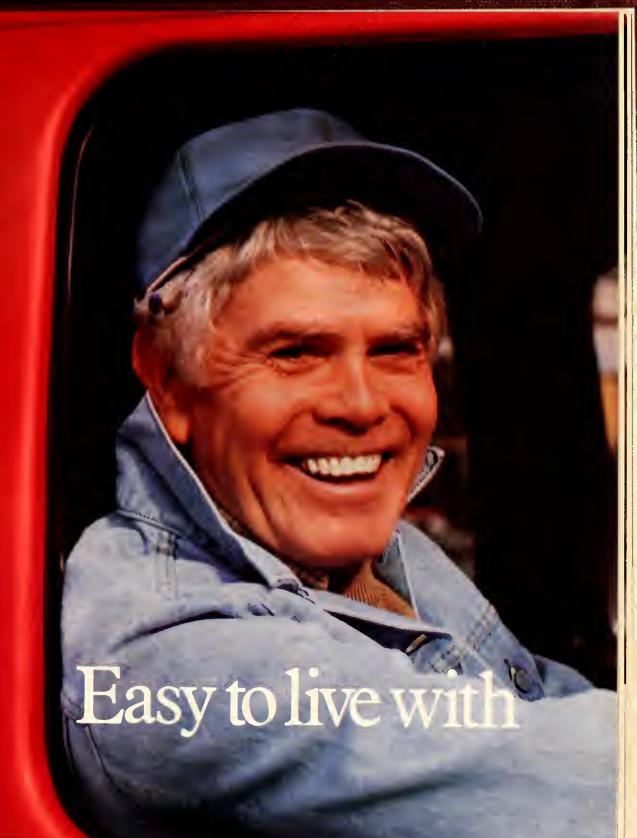
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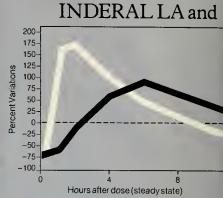
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#### CONTRAINDICATIONS

Propranolol hydrochloride (INDERAL® LA): Propranolol is contraindicated in 1) cardiogenic shock, 2) shuis bradycardia and greater than first degree block, 3) bronchal astimut, 4) congestive heart sature (see WARNINGS) unless the failure is secondary to a tachyarhythmia

**Hydrochlorothiazide:** Hydrochlorothiazide is contraindicated in patients with anuria or ypersensitivity to this or other sulfonamide-derived drugs

WARRINGS
Propranolol hydrochloride (INDERAL® LA): CARDIAC FAILURE Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close bellow-up in patients with a history of failure who are well compensated, and are receiving digitals and diuretics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitals on heart muscle.

digitals and diuretics beta-adrenergic biocoming agents of the digitals on heart muscle. 
IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propranolol should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction following abrupt discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned the dosage should be gradually reduced and the patient carefully monitored in addition, when propranolol represented for angina pectors, the patient should be cautioned against interruption or cessation of therapy without the physicians advice if propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol theraps and take other measures appropriate for the management of unstable angina pectors. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS Beta blockade may mask certain clinical signs of hyperthyroidism Theretore, abrupt withdrawal of propranoloil may be followed by an exacerbation of symptoms of hyperthyroidism, including thyroid storm, Propranoloil does not distort thyroid function lesis. IN PATIENTS WITH WOLFF-PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranoloil, the tachycardia was replaced by a severe bradycardia requiring a demand pace-maker in one case this resulted after an initial dose of 5 mg propranoloil MAJOR SURGERY. The necessity or desirability of withdrawal of beta-blocking therapy prior to major surgery is controversal! It should be noted, however, that the impaired ability of the heart to respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical procedures.

procedures

Monallergic Bronchospasm (eg, chronic bronchitis, emphyseme)—PATIENTS

WTH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS

INDERAL should be administered with caution, since it may block bronchodiation produced by
endogenous and exogenous catecholamine stimulation of beta receptors

DIABETES AND HYPOGLYCEMIA Beta-adreneige blockade may prevent the appearance of
certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in lable insulin-dependent diabetes in these patients, it may be more difficult to adjust
the dosage of insulin Hypoglycemic altacks may be accompanied by a precipitous elevation of
blood pressure.

Hydrochlorothiazide: Thrazides should be used with caution in severe renal disease In patients with renal disease, thiazides may precipitate azotemia in patients with impaired renal function, cumulative effects of the drug may develop. Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate

hepalic com may add to or potentiate the action of other antihypertensive drugs Potentiation occurs with ganglionic or peripheral advenergic blocking drugs. Sensitivity reactions may occur in patients with a history of allergy or bronchial astitima. The possibility of exacerbation or activation of systemic lupus enythematosus has been

#### **PRECAUTIONS**

PRECAUTIONS
Propranoiol hydrochioride (INDERAL® LA): GENERAL Propranoiol should be used with caution in patients with impaired hepatic or renal function Propranoiol is not indicated for the treatment of hypertensive emergencies. Beta addrenoteceptor biolockade can cause reduction of intraocular pressure. Patients should be told that propranoiol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraoutal pressure. CLINICAL LABORATIONY ETST. Elevated blood urea levels in patients with severe heard desease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase. DRUG INTERACTIONS Patients receiving catecholamine-depleting drugs, such as reserpine should be closely observed if progranoiol is administered. The added catecholamine-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncropal attacks, or or hiostatic hypotension. CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY Long terms fudies in animals have been conducted to evaluate toxic effects and carcinogenic potential. In 18-month studies, in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug induced toxicity. There were no drug-related tumorgenic effects at a granogenic bodosage levels. Reproductive studies in animals did not show any impairment of fertility that was attributable to the drug.

TREGNANCY Pregnancy Category C. Propranolol has been shown to be embryotoxic in animal studies at doses about 10 times greater than the maximal recommended human dose There are no adequate and well-controlled studies in pregnant women. Propranolol should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus

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NURSING MOTHERS. Propranolof is excreted in human milk. Caution should be exercised when

NURSING MOTHERS. Propranolof is excreted in human milk. Caution should be exercised when propranolof is administered to a nursing mother. PEDIATRIC USE. Safety and effectiveness in children have not been established. Hydrochlorothiazide: GENERAL. Periodic determination of serum electrolytes to detect possible electrolyte imbalance should be performed at appropriate intervals. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte mbalance, namely. Hyponaterma, hypochloremic alkalosis, and hypokalerma. Serum and urine electrolyte determinations are particularly important when the patient is vomitting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs irrespective of cause are. Dryness of mouth, thirst, weakness, lethargy, drowsness, resitessness, muscle pains or cramps, muscular fatigue, hypotension, obguna, tachycardia, and gastromiestrial disturbances such as nauea and vomiting. Hypokalerma dray develop, especially with binsk diudesis, when severe cirrhosis is present, or during concomitant use of corticosterodors or ACTH. Interference with adequate oral electrolyte intake will also contribute to hypokalemia. Hypokalerma can sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg., increased ventricular irritability). Hypokalerma may be avoided or treated by use of potassium supplements, such as foods with a high potassium content.

Any chloride defect is generally mild and usually does not require specific treatment, except under extraordinary circumstances (as in liver or renal disease). Dilutional hyponaterma may occur in edematious patients in hot weather, appropriate therapy is welter restriction, rather than administration of salf, except in rate instances when the hyponaterma is life-threatening in actual salt depletion, appropriate replacement is the therapy of choice. Hyperrucerma may occur or frank gout may be precipitated in certain patients receivi

In the requirements in diabetic patients may be increased, decreased, or unchanged. Diabetes insulin requirements in diabetic patients may be come manifest during this additional may be added administration. If progressive renal impairment becomes evident, consider withholding or discontinuing duretic.

Il progressive renal impairment becomes evident, consider witnitiousing or described in the repy. 
This andes may decrease serum PBI levels without signs of thyroid disturbance. 
Calcium excretion is decreased by this ades Pathologic changes in the parathyroid gland with hypercalcema, and hypophosybatema have been observed in a few patients on prolonged this adel therapy five common complications of thyperparathyroidism, such as renal lithiasis, bone resorption, and peptic ulceration, have not been seen. This addes must be a seen at the responsiveness to tubocurarine carrying out tests for parathyroid function. 
The second of the responsive parathyroid in the progression of the responsiveness to tubocurarine and the parathyroid parathyroid in the progression of the responsiveness of the responsiveness of the responsiveness of the representation of the responsiveness o

the patient should stop nursing PEDIATRIC USE Safety and effectiveness in children have not been established

#### ADVERSE REACTIONS

Propranolol hydrochloride (INDERAL® LA): Most adverse effects have been mild and transient and have rarely required the withdrawall of therapy. Cardiovascular Bradycardia, congestive heart failure, intensification of AV block, hypotension, paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud

type Central Nervous System Lightheadedness, mental depression manifested by insomnia, lassitude, weakness, fatigue, reversible mental depression progressing to catalonia, visual disturbances, hallucinations, an acute reversible syndrome characterized by discrentation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics. Gastromtestinal Nausea, overfling, engastric distress, abdominal cramping, diarriea, constipation, mesenteric arterial thrombosis, sichemic collisis.

Allergic Pharyngitis and agranulocytosis, erythematous rash, fever combined with aching and

Allergic Pharyngits and agranulocytosis, erythematous rash, lever combined with aching and sore throat, laryngospasm and respiratory distress Respiratory Bronchospasm Hematologic. Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura Auto-Immune: In extremely rare instances, systemic lupus erythematosus has been reported Miscellaneous. Alopeica, LE-like reactions, psoriastform rashes, dry eyes, male impotence; and Psyronies disease have been reported rarely Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been associated with prographic.

#### Hydrochtorothiazide:

hydrocnforotniaziae:
Gastroniestnia Anorexa, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, jaundice (nitrahepatic cholestatic paundice), panorealitis, saliadaentis
Central Nervous System Dizziness, vertigo, paresthesias; headache, xanthopsia
Hemafologic: Leukopenia, agranulocytosis, thrombocytopenia, splastic anemia
Cardiovascular Orthostatic hypotension (may be aggravated by alcohol; barbiturates, or

narcotics)

Hypersensitivity Purpura, photosensitivity, rash, urticaria, necrotizing angiitis (vasculitis, cutaneous vasculitis), fever, respiratory distress, including pneumonitis, anaphylactic reactions Other Hyperglycemia, glycosuria, hyperuncemia, muscle spasm, weakness, restlessness, transent blurred vision

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapy withdrawn.

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## An Inadvertent In Vivo Osmotic Fragility Test

R. A. Antonucci, M.D., and R. I. Walker, M.D.

HEREDITARY spherocytosis is thought to afflict one of 5,000 in the United States. Now known to result from deficiency or abnormality of red cell spectrin, its expression may vary from the patient who has moderate chronic anemia with splenomegaly and the laboratory findings consonant with chronic hemolysis (increased indirect bilirubin, lactic dehydrogenase and reticulocyte count and decreased serum haptoglobin) to the person who has no anemia and insignificant evidence for hemolysis. Those with mild disease pass unnoticed until something focuses attention on their hematopoietic system. Pigment gallstones in young people (suggesting increased heme pigment metabolism) or recurrent episodes of transient anemia following infections which may be otherwise trivial are common problems leading to the diagnosis of mild hereditary spherocytosis. The patient presented here came to attention in an unusual way.

She was a 69-year-old white woman who was admitted to the hospital because of a dense left hemiparesis. Before this she had lived alone and was self sufficient. Adult onset diabetes mellitus of over ten years' duration had been controlled by oral hypoglycemic agents. She was hospitalized 23 years previously for "congestive heart failure" and seven years ago for pneumonia. Her history was otherwise unremarkable; particularly, she had not had jaundice, anemia, or symptoms suggestive of gallbladder disease. She had never had an operation. Family history was notable for heart disease but not for anemia. Her seven children were all alive and well and though none was known to be anemic none had been examined here.

Physical examination revealed an alert and oriented woman who had a left central VIIth nerve palsy and paresis of her left upper and lower extremities. Initial laboratory studies were all within normal limits except for hyperglycemia with a sodium of 148, a left bundle branch block on electrocardiogram and a right internal capsular infarct noted on computerized tomography scan of her head. Doppler studies revealed a 70% blockage of both the right and left internal carotid arteries. She was started on aspirin, 325 mg per day, Persantine, 25 mg tid, and subcutaneous heparin, 5,000 units ql2h. Diabenase, 500 mg a day, and glucatrol 10 mg bid were continued. On the seventh day she developed hemoglobinuria and anemia. On her ninth hospital day a hematology consultation was obtained.

At this time only symptoms related to her neurologic deficits were present. Her history and physical examination were unchanged from admission; no adenopathy or organomegaly was noted. Review of the admission blood smear showed no abnormalities, and spherocytes were not present. Blood smears made during the hemolytic episode showed a small number of spherocytes and polychromasia. Laboratory data are shown in table 1.

During the hemolytic episode her plasma and urine contained much hemoglobin. Plasma hemoglobin was 239 mg/dl on day nine and lactic dehydrogenase was 3498. The direct Coomb's test and a sugar water test were negative. There were no cold agglutinins. Haptoglobin on the ninth hospital day was 5 mg/dl. The prothrombin time, partial thromboplastin time and thrombin clotting times were normal throughout her hospital stay. She had been on 1/4 normal saline at the rate of 150 ml/hr since her first hospital day. These i.v. fluids were discontinued, and the hemolytic episode promptly resolved. An osmotic fragility test performed after the resolution of the acute episode showed an increased fragility after 24 hours' incubation.

This patient, on receiving intravenous hypotonic saline, developed intravascular hemolysis with hemoglobinemia, hemoglobinuria, increased indirect bilirubin, increased lactic dehydrogenase and a drop in hematocrit from 42% to 25% over a five-day period. There was no clinical or laboratory evidence for infection, disseminated intravascular coagulation, malignancy, thrombotic thrombocytopenic purpura, cold agglutinins, paroxysmal cold hemoglobinuria or paroxysmal nocturnal hemoglobinuria. The hemolytic process resolved after the discontinuation of i.v. fluids and subsequent studies showed an increased osmotic fragility of her red cells on incubation for 24 hours. She no doubt has hereditary spherocytosis which was clinically inapparent due to the mild nature of her disease. The administration of hypotonic fluids obviously performed an in vivo osmotic fragility test. Hemolysis in this patient was not detected until she had received hypotonic fluids for about a week. Calculated serum osmolalities were within the normal range thoughout hospitalization but unfortunately were not measured. Although some increase in red cell destruction may have occurred early on, hemoglobinuria was not observed until

Why this long delay occurred is not known but it might relate to fluctuations in our patient's blood glucose concentrations. Her food intake was greatly diminished from the sixth through the twelfth days of hospitalization. The indications for giving her hypotonic fluids intravenously are not clear. Instances where this form of hydration would be appropriate must be very uncommon. If a patient appears to have lost much more water than salt, isotonic

From the Department of Medicine, The University of North Carolina, Chapel Hill 27514.

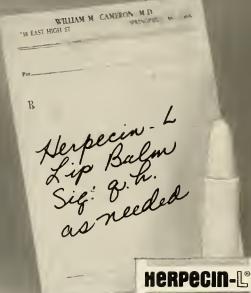
Table 1 Laboratory Data

Hospital day	Hemoglobin/ hematocrit	Reticulocyte count	Total billrubin (in- direct)	Lactic dehydro- genase	Plasma hemoglobin
2	14.3/41.9	ND	0.5	227	ND
8	13.4/39.2	2.5%	2.4 (2.0)	ND	ND
12	8.7/25.0	6.3%	ND	1087	16.4
18	11.0/31.2	2.6%	ND	ND	ND

dextrose in water and, in a diabetic, supplemental insulin, would be more appropriate. She would not appear to have required hypotonic hydration and was unnecessarily sub-

jected to intravascular hemolysis because of undetected hereditary spherocytosis. An in vitro osmotic fragility test would have been more in order.

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## PROGRAM

# 132nd Annual Session North Carolina Medical Society

April 30-May 4, 1986 Grove Park Inn Asheville, North Carolina

### DAILY SCHEDULE

W	ednesday, April 30, 1986	2:00 p.m 5:00 p.m.	Reference Committee III (Laurel H & J)
2:00 p.m	Registration (Sammons Wing Lobby)	3:30 p.m	Auxiliary Resolution Hearing
5:00 p.m.	Registration (Sammons Wing LODDy)	5:30 p.m.	(Rhododendron K & L)
2:00 p.m	N.C. Academy of Family Physicians	6:00 p.m	ECU School of Medicine Alumni
5:00 p.m.	Committees (Heritage C)	7:30 p.m.	Reception (Sunset Terrace, north
2:00 p.m	Blue Shield Committee (Laurel)	6.00	end)
5:00 p.m.		6:00 p.m 7:30 p.m.	Bowman Gray School of Medicine
2:00 p.m	Medical Mutual Insurance Company	7.50 p.m.	Alumni Reception (Sunset Terrace, south end)
5:00 p.m.	Risk Management Seminar (Blue	6:00 p.m	Duke University School of Medicine
7.00	Ridge Ballroom)	7:30 p.m.	Alumni Reception (Pool Terrace)
2:00 p.m 5:00 p.m.	Mediation Committee (Grove Room)	6:00 p.m	UNC School of Medicine Alumni
6:30 p.m	Exhibitors' Reception (Pool Terrace)	7:30 p.m.	Reception (Country Club Patio)
8:00 p.m.	Exhibitors Neception (Poor Terrace)	6:00 p.m	Medical College of Virginia Alumni
о.оо р.п.		7:30 p.m.	Reception (Laurel H)
		7:30 p.m	N.C. Pediatric Society Executive
		11:00 p.m.	Committee Dinner (Rhododendron M & N)
	Thursday May 1 1006	8:00 p.m	Medical Mutual Insurance Company
	Thursday, May 1, 1986	11:00 p.m.	Board of Directors (Rhododendron K & L)
7:00 a.m	AMA Delegation Breakfast (Laurel		
9:00 a.m.	H&J)		
7:00 a.m 10:00 a.m.	N.C. Academy of Family Physicians		
8:00 a.m	Board Breakfast (Heritage C)		Friday, May 2, 1986
5:00 p.m.	Registration (Sammons Wing Lobby)		111day, Iviay 2, 1900
9:00 a.m	Exhibits (Heritage A & B, Heritage	8:00 a.m	Posistration (Community 147)
5:00 p.m.	Lobby and Carolina Walk)	5:00 p.m.	Registration (Sammons Wing Lobby)
9:30 a.m	House of Delegates (Blue Ridge	8:30 a.m	N.C. Pediatric Society Executive
12:00 N	Ballroom)	10:00 a.m.	Committee Breakfast (Grove
10:00 a.m	N.C. Commission for Health Services		Room)
12:00 N	(Forest Room)	9:00 a.m	Exhibits (Heritage A & B, Heritage
12:00 N-	MEDPAC Luncheon (Pool Terrace)	5:00 p.m.	Lobby and Carolina Walk)
2:00 p.m.	Defended Committee Land	9:00 a.m	Section on Urology (Rhododendron
2:00 p.m 5:00 p.m.	Reference Committee I (Blue Ridge Ballroom)	12:00 N	K&L)
2:00 p.m	Reference Committee II (Heritage C)	9:00 a.m	Section on Allergy & Clinical
5:00 p.m.	ricierence communee ii (nemage C)	12:00 N	Immunology (Rhododendron M & N)

#### Section on Surgery (Essex Room, Country Club)

CHAIRMAN: Walter J. Pories, M.D., Greenville, N.C.

	Taiter B. 1 of test times, at comment
9:00 a.m	Opening Remarks
9:05 a.m.	Walter J. Pories, M.D., Greenville,
	N.C.
9:05 a.m	"The Role of Surgery in the
9:25 a.m.	Treatment of Acute Myocardial
	Infarction"
	W. Randolph Chitwood, Jr., M.D.,
	Greenville, N.C.
9:25 a.m	"Surgical Problems of the Respiratory
9:45 a.m.	Tract in Infants and Children"
	Erle H. Austin, III, M.D.,
	Greenville, N.C.
9:45 a.m	"New Advances in Critical Care and
10:05 a.m.	Burn Wound Management"
	Anthony A. Meyer, M.D., Ph.D.,
	Chapel Hill, N.C.
10:05 a.m	Discussion Period
10:20 a.m.	
10:20 a.m	Break
10:40 a.m.	
10:40 a.m	"New Horizons in Transplantation"
11:00 a.m.	Francis T. Thomas, M.D.,
	Greenville, N.C.
11:00 a.m	"Modern Techniques of Breast
11:20 a.m.	Reconstruction"
	Donald Serafin, M.D., Durham,
44.00	N.C.
11:20 a.m	"International Health Care Delivery —
11:40 a.m.	What Role Can We Play?"
	Timothy C. Pennell, M.D.,
11.40 nm	Winston-Salem, N.C. Discussion Period
11:40 a.m	Discussion Period
11:55 a.m.	Dusiness Meetine
11:55 a.m	Business Meeting
12:00 N	

9:00 a.m	First General Session/Second General
12:00 N	Session (Blue Ridge Ballroom)
9:30 a.m	Officers' Spouse Brunch (Regent
11:00 a.m.	Room, Country Club)
10:00 a.m	NCSIM Third Party Liaison Committee
12:00 N	(Windsor Room, Country Club)
10:00 a.m	N.C. Pediatric Society Liaison
1:30 p.m.	Committee (Pine Room)
11:00 a.m	N.C. Orthopaedic Association
1:00 p.m.	Executive Committee (Sun Room,
•	Fox & Hounds Restaurant, Country

Club)

## Section on Ophthalmology/N.C. Society of Ophthalmology (Forest Room)

CHAIRMAN: L. Franklin Cashwell, Jr., M.D., Winston-Salem, N.C.

PROGRAM CHAIRMAN: James B. Sloan, M.D., Wilmington, N.C.

Wilmington,	N.C.
12:00 N- 2:00 p.m.	Luncheon/Business Meeting
2:00 p.m	"Magnetic Resonance Imaging"
2:10 p.m.	Baird S. Grimson, M.D., Chapel Hill, N.C.
2:10 p.m	"Cerebrospinal Fluid Masquerading as
2:20 p.m.	Tears"
	Jonathan S. Till, M.D., Winston- Salem, N.C.
2:20 p.m	"Transient Binocular Effects of
2:30 p.m.	Retrobulbar Anesthesia"
	Paul J. Simel, M.D., Greensboro,
	N.C.
2:30- p.m	Discussion
2:45 p.m.	
2:45 p.m	"Acanthamoeba Keratitis"
2:55 p.m.	Edward K. Isbey, M.D., Durham,
	N.C.
2:55 p.m	"Vitamin A Deficiency in North
3:05 p.m.	Carolina"
	Kent W. Small, M.D., Durham,
	N.C.
3:05 p.m	"Nutritional Therapy in the
3:15 p.m.	Cataractous Patient"
	Gary P. Todd, M.D., Waynesville, N.C.
3:15 p.m	"Blepharopigmentation"
3:25 p.m.	E. E. Moore, M.D., Asheville, N.C.
3:25 p.m	Discussion Period
3:35 p.m.	
3:35 p.m	Break
4:00 p.m.	
4:00 p.m	"Blindness, Glaucoma and Ocular
4:10 p.m.	Hypertension"
	Roy Whitaker, M.D., Lynn, Mass.
4:10 p.m	"Cryotherapy in the Treatment of

4:10 p.m.4:20 p.m.

"Cryotherapy in the Treatment of Retinopathy of Prematurity"
Edward G. Buckley, M.D.,
Durham, N.C.

4:20 p.m.
The Effect of Panretinal

4:25 p.m. Photocoagulation on Contrast Sensitivity and Visual Acuity"

Jerome J. Magolan, Jr., M.D.,

Raleigh, N.C.
"Diabetic Retinopathy and

4:35 p.m. Pseudophakia"

4:25 p.m.-

Gregory I. Mincey, M.D., Southern Pines, N.C.

4:35 p.m.- Discussion Period 5:00 p.m.

## Section on Emergency Medicine (Laurel H & J)

#### CHAIRMAN: Marsha Ford, M.D., Charlotte, N.C.

2:00 N-	North Carolina Chapter, American
2:00 p.m.	College of Emergency Physicians
2:00 p.m	Business Meeting
2:45 p.m.	_
2:45 p.m	"Trauma Scoring Systems"
3:30 p.m.	Richard Bois, M.D.
	Dan Sayers, M.D.
3:30 p.m	"Acetominophen Overdose"
4:15 p.m.	Marshall McCoy, M.D.
·	Kathleen Cline, M.D.
4:15 p.m	"Use of Streptokinase in the Setting
5:00 p.m.	of an Acute MI"
•	John Santamaria, M.D.
	Marsha Ford, M.D.

1:00 p.m.2:00 p.m. N.C. Orthopaedic Association Business
Meeting (Essex Room, Country
Club)

#### Section on Pediatrics (Heritage C)

CHAIRMAN: George E. Prince, M.D., Gastonia, N.C.

2:00 p.m	"Update on the Immunization of
2:30 p.m.	Children''
	Catherine M. Wilfert, M.D.,
	Durham, N.C.

2:30 p.m.3:00 p.m. "Present Legislation Concerning Immunization of Children in North Carolina"

David T. Tayloe, Jr., M.D., Goldsboro, N.C.

3:00 p.m.- Business Meeting 3:15 p.m.

## Section on Family Practice (Laurel F&G)

CHAIRMAN: C. Franklin Church, M.D., Raleigh, N.C.

PROGRAM CHAIRMAN: Charles O. Boyette, M.D., Belhaven, N.C.

2:00 p		"Adverse Reactions to Newer
3:00 p.	.m.	Antidepressants"
		Peggy Hayes, Richmond, Virginia
		(Sponsored by Mead Johnson
		Pharmaceutical Group)
3:00 p.	.m	"Update on Treatment of Alcoholism"
4:00 p.	m.	J. Paul Martin, M.D., Asheville,
_		N.C.
4:00 p.	m	"Grieving"
4:55 p.	m.	P. Richard Olson, M.D., Asheville,
		N.C.
4:5S p.	m	Business Meeting

Section on Obstetrics & Gynecology (Mid Pines Resort, Southern Pines. N.C.) CHAIRMAN: Stephen G. Anderson, M.D., Winston-Salem, N.C.) 2:00 p.m.-"Alpha Fetoprotein Screening for 2:30 p.m. Neural Tube Defects -Responsibilities for Obstetricians" John Seeds, M.D. 2:30 p.m.-"Experience with Neural Tube 3:00 p.m. Screening in North Carolina" Barbara Burton, M.D. 3:00 p.m.-"Methodology for Testing for Torch 3:30 p.m. Titers, Chlamidia, Alpha Fetoprotein and Other Antibodies" Sam Pegram, M.D. 3:30 p.m.-Break 4:00 p.m. 4:00 p.m.-"The Effect of Increased Malpractice 4:30 p.m. Premiums on the Delivery of Health Care in North Carolina"

4:30 p.m.5:00 p.m.

Senator Thomas F. Taft
5:00 p.m.5:05 p.m.

Senator Senator Thomas F. Taft
Business Meeting

Resources

Phillip J. Kirk, Jr., Secretary N.C. Department of Human

## Section on Infectious Diseases (Rhododendron K & L)

#### CHAIRMAN: Harry A. Gallis M.D. Durham, N.C.

CHAINWAIN:	narry A. Gallis, M.D., Durnam, N.C.
2:00 p.m	"Viral Infections of Central Nervous
2:30 p.m.	Systems"
·	Sam Katz, M.D., Durham, N.C.
2:30 p.m	"Rocky Mountain Spotted Fever"
3:00 p.m.	Terrence Lee, M.D., Asheville, N.C.
3:00 p.m	"Coagulase Negative Staphylococcal
3:30 p.m.	Infection"
-	Herbert Clegg, M.D., Charlotte,
	N.C.
3:30 p.m	"Manifestations of TB in the
4:00 p.m.	Community Hospitals"
	James Horton, M.D., Charlotte,
	N.C.
4:00 p.m	"Resistance to Tuberculosis"
4:30 p.m.	Bruce Campbell, M.D., Greenville,
	N.C.
4:30 p.m	"Differential Diagnosis of Hepatitis"
5:00 p.m.	Stanley Lemon, M.D., Chapel Hill,
	N.C.
5:00 p.m	Business Meeting
5:05 p.m.	•

2:00 p.m.- Section on Public Health & Education 5:00 p.m. (Windsor Room, Country Club)

5:00 p.m.

Section on Orthopaedics (Essex Room, Country Club)		
CHAIRMAN: A.	Tyson Jennette, M.D., Wilson, N.C.	
2:00 p.m 3:00 p.m. 3:00 p.m 4:00 p.m	"Antitrust Compliance" George L. Little, Jr., Winston-Salem, N.C. "Pediatric Orthopaedics" John Denton, M.D., New York, N.Y. Orthopaedic Papers	
5:00 p.m. 5:00 p.m. 5:05 p.m.	speakers to be determined Business Meeting	

2:00 p.m	N.C. Society of Internal Medicine
5:00 p.m.	Executive Committee (Oxford Room, Country Club)
E 00	
5:00 p.m	N.C. Society of Internal Medicine
6:30 p.m.	Reception (Drawing Room and
·	Patio, Country Club)
6:30 p.m	President's Reception (Sunset
7:30 p.m.	Terrace)
7:30 p.m	President's Dinner & Dance (Blue
12:00 M	Ridge Ballroom)
7:30 p.m	Registration — N.C. Chapter,
9:00 p.m.	American College of Radiology
	(Prefunction Area of Heritage C)
7:30 p.m	N.C. Chapter, American College of
9:00 p.m.	Radiology Reception (Heritage C)

#### Saturday, May 3, 1986

8:00 a.m.- Registration (Sammons Wing Lobby) 3:00 p.m.

Section on Anesthesiology (Laurel F&G)

CHAIRMAN: H. Ryland Vest, M.D., Raleigh N.C. 8:00 a.m.- "Minimizing Perioperative Cardiac 8:50 a.m. Risk"

Glen Gravlee, M.D. 8:50 a.m.-9:40 a.m. Gordon Mandell, M.D.

9:40 a.m.- Break 10:10 a.m.

10:10 a.m.11:00 a.m.
Raymond C. Roy, M.D.
11:00 a.m.Business Meeting

11:00 a.m.- Business Meeting

8:00 a.m.- Registration — N.C. Chapter, 12:00 N American College of Radiology (Prefunction Area of Heritage C)

Section on Radiology/N.C. Chapter American College of Radiology (Heritage C) CHAIRMAN: Larry M. Crane, M.D., Durham, N.C. 8:00 a.m.-"Patterns in Neurodiagnosis" 8:45 a.m. James G. Smirniotopoulos, M.D., Washington, D.C. 8:45 a.m.-"Renal Angioplasty" 9:45 a.m. Charles J. Tegtmeyer, M.D., Charlottesville, Virginia 9:45 a.m.-"Current Clinical Applications of 10:15 a.m. SPECT Scanning James H. Zuger, M.D., Charlotte, N.C. 10:15 a.m.-8reak 10:45 a.m. 10:45 a.m.-"Multimodality Imaging in Staging of 11:30 a.m. Lymphomas" R. Kristina Gedgaudes-McClees, M.D., Atlanta, Georgia 11:30 a.m.-"Fishing for the Interventional 12:15 p.m. Radiologist" Charles J. Tegtmeyer, M.D., Charlottesville, Virginia

Section on Pathology (Forest Room) CHAIRMAN: Henry A. Wilkinson, M.D., Charlotte, N.C. 8:30 a.m.-"Hurthle Cell Lesions of the Thyroid" 9:00 a.m. R. Lee West, M.D., Greenville, N.C. 9:00 a.m.-Wiley Forbus Award Presentation 9:30 a.m. 9:30 a.m.-Break 9:45 a.m. 9:45 a.m.-"Current Socioeconomic Situation in 10:45 a.m. Pathology" speaker to be determined 10:45 a.m.-**Business Meeting** 11:30 a.m.

Section on Dermatology (Heritage A) CHAIRMAN: R. Wade Markham, M.D., High Point, N.C. 9:00 a.m.-"Etretinate - An Overview" 9:30 a.m. Tom Frenz, M.D., Hoffman-LaRoche Laboratory "Cosmetics in Dermatology" 9:30 a.m.-10:45 a.m. Nia Terezakis, M.D., New Orleans, Louisiana 10:45 a.m.-Break 11:00 a.m. 11:00 a.m.-"Allergic Reactions to Cosmetics" 11:20 a.m. Stan Levy, M.D., Almay Cosmetics "Diseases and Conditions Aggravated 11:20 a.m.-11:40 a.m. or Helped by Cosmetics" Gloria Graham, M.D., Wilson, N.C. "New Chemicals in Cosmetics" 11:40 a.m.-12:00 N Peter Kaufmann, Almay Cosmetics 12:00 N-**Business Meeting** 12:05 p.m.

		The state of the s
		on on Otolaryngology &
		xillofacial Surgery (Laurel H & J)
		dgar C. Garrabrant, M.D., Raleigh, N.C.
	9:00 a.m	"Chronic Osteomyelitis of the Maxilla"
	9:15 a.m.	Eric M. Kraus, M.D., Greensboro,
	6.19	N.C.
1	9:15 a.m	"Update on Melkersson-Rosenthal
	9:30 a.m.	Syndrome"
		Eric M. Kraus, M.D., Greensboro, N.C.
	9:30 a.m	"Testing for Food Allergies"
	9:45 a.m.	Walter A. Ward, M.D., Winston-
	5.45 a.m.	Salem, N.C.
	9:45 a.m	"The Zygoma — A Rosetta Stone"
	10:00 a.m.	Walter Sabiston, M.D., Kinston,
		N.C.
	10:00 a.m	"Miniplate Fixation for Zygomatic
	10:15 a.m.	Fractures"
		James L. Darsie, M.D., Lenoir, N.C.
	10:15 a.m	"Unique Middle Ear Problems"
	10:30 a.m.	Lynn A. Hughes, M.D., Concord,
	10-20 2 5	N.C.
	10:30 a.m 10:45 a.m.	"Laryngeal Framework Surgery: Laryngoplasty"
	10:45 a.m.	James Koufman, M.D., Winston-
		Salem. N.C.
	10:45 a.m	"Mucormycosis of the Head and
	11:00 a.m.	Neck"
		Stuart Owens, M.D., Durham, N.C.
		Joseph Farmer, M.D., Durham,
		N.C.
	11:00 a.m	"Laryngeal Trauma"
	11:15 a.m.	Keith Walvoord, M.D., Durham, N.C.
		Boyce Cole, M.D., Durham, N.C.
	11:15 a.m	"New Cochlear Implants"
	11:30 a.m.	Harold C. Pillsbury, M.D., Chapel
		Hill, N.C.
	11:30 a.m	"Steroids and Postintubation Croup"
	11:45 a.m.	Charles Woods, M.D., Chapel Hill,
		N.C.
		Duncan Postma, M.D., Chapel Hill,
	11.45	N.C.
	11:45 a.m 12:00 N	Business Meeting
	12:00 N	

	Section on Neurological Surgery (Pine Room)		
١	CHAIRMAN: Stephen C. Boone, M.D., Raleigh, N.C.		
ı	9:00 a.m	"Malpractice Legislation"	
١	10:00 a.m.	Group Discussion	
ı	10:00a.m	"Neurological Surgery Case	
l	11:00 a.m.	Presentations"	
		Robert L. Timmons, M.D.,	
		Greenville, N.C.	
ı	11:00 a.m	Business Meeting	
	12:00 N	· ·	
	12:00 N-	Luncheon	
	1:30 p.m.		

Section on Internal Medicine (Heritage B)				
CHAIRMAN: Charles Allan Eure, M.D., Raleigh, N.C.				
9:00 a.m	"Reflux Esophagitis"			
9:25 a.m.	Eugene Bozymski, M.D., Chapel			
	Hill, N.C.			
9:25 a.m	"Management of Acute Myocardial			
9:50 a.m.	Infarction"			
	James Scanlan, M.D., Raleigh, N.C.			
9:50 a.m	"Management of Community and			
10:15 a.m.	Hospital Acquired Pneumonias"			
	Timothy Lane, M.D., Greensboro, N.C.			
10:15 a.m	"New Therapies for Rheumatoid			
10:40 a.m.	Arthritis"			
10.40 4.111.	Richard Polisson, M.D., Durham,			
	N.C.			
10:40 a.m	Break			
10:55 a.m.				
10:55 a.m	"Asymptomatic Myocardial Ischemia"			
11:20 a.m.	David Pearle, M.D., Washington,			
	D.C.			
11:20 a.m	"Peptic Ulcer Disease: Cytoprotection"			
11:45 a.m.	Ray Orlando, M.D., Chapel Hill,			
44.45	N.C.			
11:45 a.m	Business Meeting			
12:00 N				

_			
	Section on Psychiatry (Rhododendron		
	M & N)		
	CHAIRMAN: Anthony Weisenberger, M.D., Asheville,		
	N.C.		
	9:00 a.m	"The Neuroleptic Malignant	
	9:45 a.m.	Syndrome"	
		Robert Wells, M.D., Asheville, N.C.	
	9:45 a.m	"Update on Neurobiology, Dementia	
	10:30 a.m.	and Behavioral Effects of Epilepsy"	
		H. William Gillen, M.D.,	
		Wilmington, N.C.	
	10:30 a.m	Break	
	10:45 a.m.		
	10:45 a.m	"Update on Neuroendocrine Testing	
	11:30 a.m.	and Plasma Levels of Psychotropic	
		Drugs in Clinical Practice"	
		Kenneth Jobson, M.D., Knoxville,	
		Tennessee	
	11:30 a.m	Business Meeting	
	12:00 N	3	

Section on Medical Students (Ascot Room, Country Club)				
CHAIRMAN: Melisa Moore, Chapel Hill, N.C.				
	Recap of 1985-1986 Projects			
10:00 a.m.	A. Scholarship			
	B. Newsletter			
10:00 a.m	Plans for 1986-1987			
11:00 a.m.	A. Membership			
	B. Section Activities			
11:00 a.m	Business Meeting			
12:00 N				

Section on Hospital Medical Staffs (Regent Room, Country Club)

CHAIRMAN: Courtland H. Davis, Jr., M.D., Winston-Salem, N.C.

"Credentialing and Hospital Privileges" 9:00 a.m.-Preecha Bhotiwihok, M.D., 10:00 a.m. Kinston, N.C.

"Issues Affecting the Hospital Medical 10:00 a.m.-

11:00 a.m. Staff"

Group Discussion **Business Meeting** 

11:00 a.m.-12:00 N

9:00 a.m.-Section on Resident Physicians 12:00 N (Oxford Room, Country Club)

> Section on Neurology (Rhododendron K & L)

CHAIRMAN: H. William Gillen, M.D., Wilmington, N.C.

11:30 a.m.-**Business Meeting** 

12:00 N

12:00 N-Section on Dermatology Luncheon 2:00 p.m. (Heritage A) 12:00 N-New Hanover-Pender County Medical 1:30 p.m. Society Lunch & Caucus (Essex Room, Country Club) 12:15 p.m.-Section on Neurological Surgery 2:00 p.m. Luncheon (Pine Room) 12:30 p.m.-Pitt County Medical Society Lunch & 1:30 p.m. Caucus (Forest Room) 1:00 p.m.-Mecklenburg County Medical Society 2:00 p.m. Caucus (Laurel F & G) 1:00 p.m.-Forsyth-Davie-Stokes County Medical 2:00 p.m. Society Caucus (Laurel H & J) 1:00 p.m.-N.C. Society of Plastic, Reconstructive 2:00 p.m. and Maxillofacial Surgery Board of Directors Luncheon (Grove Room) 2:00 p.m.-N.C. Society of Plastic, Reconstructive 4:00 p.m. and Maxillofacial Surgery Business Meeting (Rhododendron M & N) 2:00 p.m.-House of Delegates (Blue Ridge 5:00 p.m. 5:00 p.m.-N.C. Society of Plastic, Reconstructive 8:00 p.m. and Maxillofacial Surgery Reception and Dinner (Heritage A) 7:00 p.m.-N.C. Chapter, American College of 8:00 p.m. Radiology Reception (Drawing Room and Patio, Country Club) 8:00 p.m.-N.C. Chapter, American College of 9:30 p.m. Radiology Dinner (Windsor Room,

Country Club)

#### Sunday, May 4, 1986

8:00 a.m.-12:00 N

Registration — N.C. Chapter, American College of Radiology (Prefunction Area of Heritage C)

Section of Radiology/N.C. Chapter, American College of Radiology (Heritage C)

CHAIRMAN: Larry M. Crane, M.D., Durham, N.C.

8:00 a.m.-"Complications of Pancreatitis" 8:45 a.m. R. Kristina Gedgaudes-McClees.

M.D., Atlanta, Georgia 8:45 a.m.-"Computed Tomography of 10:00 a.m. Cerebrovascular Disease"

James G. Smirniotopoulos, M.D.,

Washington, D.C.

10:00 a.m.-Break 10:30 a.m.

10:30 a.m.-"Percutaneous Lung Abscess

11:15 a.m. Drainage"

James H. Zuger, M.D., Charlotte,

11:15 a.m.-"Report From the American College of 11:45 a.m. Radiology"

11:45 a.m.-**Business Meeting** 12:00 N

# YEAR OFTHE E R

## North Carolina Medical Journal

## Features for Patients

April 1986

### The Carolina Organ Procurement Agency (A Cooperative Approach to Organ/Tissue Recovery in North Carolina)

Stephen L. Joyner

Transplantation and organ donation have seen a recent upsurge in public attention resulting in increasing medio coverage and the passage of the National Transplantation Act in October of 1984. Much of this is due to the increased success rate of multi-organ transplantation and to pleas of recipient families for financial support and for organs ta be donated so that their loved ones might live.

As a direct result of the National Transplantation Act, a task force was formed to study all aspects of transplantation, organ recovery and the need for a national registry far transplant recipients. One of the charges to the task force was that it look of ways in which organ donation might be increased throughout the United States. There is still a tremendous shortage of organs and tissues for transplant. Many recipients wait months to years before receiving a transplant and many do not survive long enough to receive a transplant.

In North Carolina there are five medical institutions currently involved in organ/tissue tronsplantatian. Those centers are Charlotte Memorial Hospital, Charlotte; Bowman Gray School of Medicine, Win-

stan-Solem; Memorial Hospital, Chapel Hill; Duke Hospital, Durham; Pitt County Memorial Hospital, Greenville. Organs and tissues currently being transplanted include kidneys, hearts, livers, corneas, bone and skin. The shortage of organs and tissues for transplant stimulated the North Carolina Kidney Council to develop an organ recovery committee made up of professionals from all five transplant programs to study organ and tissue recovery in North Carolina and how it might be enhanced. Two types of organ recovery programs were looked at: (1) hospital-based programs which, for the most part, were utilized by the five transplant centers in North Corolina and (2) the independent organ recovery program.

The hospital-bosed programs are run by individual hospitals with funding intermingled in their total hospital budgets. The personnel are utilized in several areas, not just organ recovery. This situation frequently led to less than adequate funding to perform the services needed to recover organs and tissues, as well as multiple use of manpower, taking away from the mojor thrust of organ and tissue recovery. An independent organ procurement program maintains a budget that is totally directed toword the organ and tissue

recovery effort of that agency. The manpower utilized is directed 100% toward organ and tissue recovery. Because the ogency is autonomous from other institutions, it thereby can direct its efforts solely toward the recovery of organs and tissues.

In the comparative study by the North Carolina Kidney Council, it was quite clear that the independent organ procurement ogency was a much more effective agency in the area of organ and tissue recovery. As a direct result of this study, three of the tronsplant centers in eastern North Corolina — Duke University Hospital, East Carolina University School of Medicine and North Carolina Memorial Hospital — began to discuss developing an independent organ procurement ogency to serve the eastern half of North Corolina and to provide argans and tissue for tronsplant.

Charlotte Memorial Hospital and Bowman Gray School of Medicine, were consulted about the formation of the Carolina Organ Procurement Agency. Both expressed some interest in a statewide organization. They share some common concerns relevant to the lang standing employees in their own programs and how they might fit into a new program and wanted to wait and see if the Carolina Organ Procurement Agency was a successful venture for the three par-

Fram the Carolina Organ Procurement Agency, 400 Eastawne Drive, Chapel Hill 27514. ticipating transplant centers before becaming actively invalved. It is natewarthy that these two centers have been invited to all the arganizational meetings as well as the angaing Board of Director meetings of the Caralina Organ Pracurement Agency and thus are in a position not anly to be informed but also to have some input into the development of the Corolino Organ Pracurement Agency.

After a period of some six months, the Caralina Organ Pracurement Agency was developed and incorporated in the state of North Caralina as a non-prafit service agency an April 4, 1985. It is directed by a Board of Directars appainted by the three porticipating transplant centers. It has twa primary offices, one located in Greenville, (Building N, Physicions Quadrangle) and the other located in Chapel Hill (Eastowne Office Park, Building 400, Suite 109). These two offices were strategically located to focilitate quick respanse when dealing with any of the tronsplant centers and the 56 haspitals in the service area.

The Eastern office is stoffed by the executive director, the supervisor caardinator, two procurement caordinators, an accountont, an administrative secretory and a general secretary. The Triangle office is staffed by a supervisor caordinator, three pracurement coordinators, and a general secretary. All the procurement coordinators are either registered nurses or physician assistants.

The purpose of the Corolino Organ Procurement Agency is to develop o cooperative effort with all of the haspitals in the service area to recover argans and tissues. Our most important goal is to facilitate increased organ donation and to provide acceptable organs and tissues for transplant by the following methods:

- A. Identify potential organ/tissue donars.
- B. Evaluate patential argan/tissue donors as to acceptable criteria.
- C. Work with the hospital adminis-

- tratian, staff and nursing service ta develop an individual program far eoch haspital with oppropriate policies and reference material to facilitate all types af onatamical danatian within each institution.
- Caardinate within each hospital the process of organ/tissue danation, recovery and placement.
- E. Provide professional education to the administrative medical staff and nursing staff related to argan/ tissue danar identification, management and recovery.
- F. Pravide public education in the cammunities throughout the service areo concerning the need for organ/tissue donation.
- G. Poy all casts incurred by the danar institution directly related to the act of donation. The costs relevant to kidneys are recovered from the End-Stage Renal Disease Program (i.e., Medicore). The casts for recovering all other organs and tissues are recovered from the institution that utilizes the particular argan or tissue.

By combining the previous hospital-based program, we feel that these goals can be met more effectively and at reduced casts. The North Corolino legislature was asked to assist with funding to develop this independent argan pracurement agency and hos awarded the Corolina Organ Pracurement Agency a one-time grant af \$150,000 ta establish itself as on independent nan-profit organ procurement program.

Caralina Organ Procurement Agency farmally began operating in North Corolina on July 1, 1985 with a tatal staff af seven procurement caordinates — nurses and physician assistants specially trained in the areas af donar identification, management and recovery of argans/tissues for transplant.

Same af the methods that Carolina Organ Procurement Agency will use ta accamplish its responsibilities are as follows:

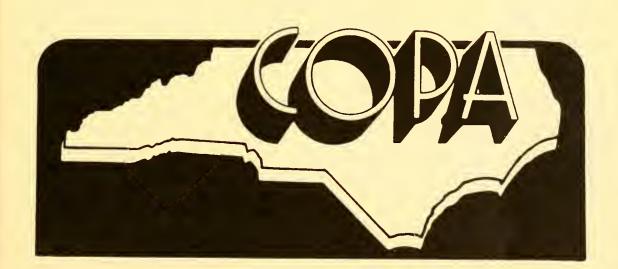
The Carolina Organ Pracurement Agency staff will meet with the administratars of each haspital in the 52-county service area. The coordinatar will explain the services available through the Carolina Organ Pracurement Agency argonization and will wark with the hospital nursing and medical staff to develop individual protacals within each hospital ta address the areas of danar identification, management and recavery. Once these pratocols have been developed and appraved, the Carolina Orgon Pracurement Agency coordinators will provide prafessional in-services to all af the hospital staff covering all areas of donar identification, monagement and recavery. The coordinators will also develop a cammunity-based program of public education that includes speaking with various social and business clubs, church arganizations, school organizations and other public service groups. These tolks will address the need for argans/tissues for transplant and the information needed to make a decision concerning argan/ tissue donation. The caardinators will participate at health fairs and other organized events throughout the service area to provide information ta the public of large cancerning orgon/tissue donotion. In the event of an actual anatamical danation within the service orea, the Carolina Organ Procurement Agency coordinator is on 24-hour call and will be dispatched ta the donor institution to coordinate oll of the activities. This includes such things os reviewing the patient's histary with the attending physician, discussing the organ/tissue donotion with the next of kin, abtaining cansent, caardinating the vorious groups involved in management and recovery af organs/tissues for transplant, processing and placing the donated tissue throughout the Caralina Organ Pracurement Agency service area.

The Caralina Organ Procurement Agency staff will then send the donar family follow-up information concerning the placement and use of danated tissue and will pravide this infarmation to the medical and nursing staff of the danor center. Carolina Organ Procurement Agency will pay all the costs incurred in the argan/tissue danation at the danor center, as well as those costs incurred in processing and transporting donated tissue to the receiving institution. There will be no cost to the donar institution nor the danor family.

Caralina Organ Pracurement Agency is affiliated with the North Carolina Eye and Human Tissue Bank. Under a service agreement between the two institutions, Caralina Organ Procurement Agency coordinatars will pravide public education and prafessional education related to the need for eye and tissue danatian, and will recover, process and place carneal tissue with the direction of the North Carolina Eye and Human Tissue Bank throughout the Carolina Organ Pracurement Agency service area. The Caralina Organ Pracurement Agency will be reimbursed for these services by the North Carolina eye and Human Tissue Bank on a monthly basis. The North Carolina Eye and Human Tissue Bank then will recover its costs

by billing the receiving institution a processing fee.

Organ/tissue donation will tauch all areas af medical practice ane way or another, sooner or later. The medical profession has an abligation to be informed on the subjects of transplantation and argan donation in arder to provide proper information to their patients and families concerning these services. The Carolina Organ Procurement Agency has a 24-haur number, 1-800-252-COPA. You may call this number at any time for more information.



#### Stoned Again

Patricia K. Hadgson

8:00 a.m. Saturday. It's nice to sleep this late. We've had two weeks af flu in both affspring, and what with their hacking all night and vomitting all day we've had to juggle work and home schedules and sleep has been the loser. So no alarm set Friday night — every minute beyond 6:30, our usual rising time, is great.

I arise and immediately wish I hadn't. Must have slept wrong. There's this pain in my back, like a muscle pull, just above my waist on the right side, over the kidney. Oh no. Please. Not a stone. I don't think I want to handle a kidney stone today.

9:00 a.m. There isn't much doubt. It hurts like a stone, it's in the right place, it doesn't change when I mave, it doesn't — unfartunately — ga away. First step: identification. Done. Second step: pain relief; call the doctor.

Doctor is in the labby of the hospital about to return to the affice and will meet my spause there with demeral far the pain. I have reached that point in the travels of this stone where it has hit a place where it has room. The pain is gone, completely, but I know it will be back, just as bad, probably in thirty minutes or sa. Spouse hurries, cuts the line at the pharmacy, asks our friendly pharmacist to fill the prescription fast, and returns in thirty minutes exactly with the demeral. Naw I need it. I take two 50 mg tablets and hope I pass the stane befare the four hours between dases is up.

I stort drinking as much water as I can stand, and then go for a walk with Child Number One, herself just out of the hospital after a bad case of the flu. We walk a mile and a half or so, and then I suggest we turn back. I'm getting a little high, and my balance is less than perfect. We stop on a bridge to watch the water ripple past in the creek below, and then must hurry on faster. The power of suggestion.

I continue pushing and passing water and start washing the kitchen windows. The pain is soon back, and it isn't the kind of pain you can go lie dawn with. It demands your attention. By noon I have checked a past issue of this Journal to see how much more relief I could get if my doctar would give me the next dose of demeral intramuscularly. I see that it would be substantially more, sa I call him at home, hurting terribly, thirty minutes or so before my next scheduled dose. He demurs, suggesting that I will just need more the next time. At the moment that hardly matters to me. He asks if I am bleeding. I am not. He asks if I am vamiting yet. I am not, but I am nauseaus. He tells me that when I start to vamit, I need to go to the emergency raom. I notice his use of the word "when," I take my next two demerol.

I've had two stones before and I know they're no fun. Both were on the left side, and both were terrible. This is on the right. Samehow this one is worse.

Within not much time the family thinks it is time to let someone else take over this stone, and I agree hesitantly. It's 1:45 p.m. and the Caralina-Clemson basketball game doesn't start until 4:00. Maybe I'll be doped up and back home in time to see some of it. We are diehard Tar Heel fans. We head for the hospital, mindful of the traffic around it and the Smith Student Activity Center, site of the game. Child Number One has

placed my packetbook, a tawel and a pail in the back seat for me. She drives. Her father navigates. I hurt. And then I vamit. At least I'm doing what I was told.

We arrive at the emergency room, enter, and register. I'm mindful that I'm leaning on the counter, head on hands, wishing someone would make it all go away. They come with a wheelchair, wheel me to a stretcher in a space with curtoins an three sides, have me remove all my clothes and put on a haspital gown. They put my clothes an a shelf under the stretcher and me on top of the stretcher. It will be my home for quite a while.

A nurse in blue comes and sticks my left wrist, taking blood and then starting an intravenous line. I hope there is samething in it for the pain. An intern arrives, asks about the trouble, listens and then departs, Another nurse in blue cames with a nicely reassuring needle in her hand, injects morphine into the IV line and leaves. A resident arrives, asks about the trouble, listens, pats my shoulder and promises to make it better, and then departs. Time passes. An aide cames with a temporary wrist tag to remind me of my name, puts it on my right wrist, and then departs.

Others came and go over the next few hours, some with more morphine, but it doesn't seem to help. I still hurt. I listen to the man in the stretcher on my left as they put a tube down his throat. He gags a lot. I listen as the lady on my right asks about the redness in her eye. They tell her she hos conjunctivitis and it is nothing to warry about, but they ask her to stay a while so they can watch her blood pressure. It's a bit law. I wonder what they thought about the gaings-on in my area.

An aide comes and asks me if I

From Box 3910, Duke University Medical Center, Durham 22710.

can give her a urine sample. I soy I'll try. We get me from the stretcher to a wheelchair, push me to a nearby bathroom. I sit in the wheelchoir, hunched over, feeling nauseous and miserable. I connot move. I don't want to move. I wonder if I could possibly look as bod os I feel. We return me to my stretcher where the resident catheterizes my bladder. A new low point.

An ottending physician in urology arrives, introduces himself, and I ask for something to handle the pain. More morphine comes. He orders an x-ray, ond they push me off to the radiology section for that. The nurse osks if the x-ray shows anything. The technician says no, but they never do. We return to emergency where spouse and child wait to visit. They look uncomfortable.

More time passes, more morphine is sent into the IV, this time accompanied by an antiemetic injected into my hip. This much morphine might moke me vomit, they say. I olready am. The attending says they want to keep me overnight. I agree. Anything. But could he do something for the pain.

The intercom asks if I can have visitors. My family arrives, complete, having been joined by Child Number Two. They look sad, worried, helpless. They say that they will go home, come back in the morning. We're all relieved.

I watch the ceiling tiles as we proceed from emergency to elevator to room. The tiles are all the same, boring. We transfer me from stretcher to bed, my clothes to a closet. The pain is still there, and I'm very tired of it. I have a double room to myself. It has a large television on the opposite wall and a clock nearly as large. The time does not register.

Soon a vision in white with squeeky shoes arrives with two substantial-looking needles in her hand. She injects the first in my right hip — another antiemetic — and the second in my left hip — more morphine. Why not inject it directly into the IV, I osk? She tells me this much morphine IV

could stop my breathing. I am strangely comforted by that news. I drift off to sleep.

I awaken when my door opens and our minister walks in. Spouse hos called him to beg off some chores we were scheduled for in church the next day, and he has come to visit. How brave to walk into the room of someone in pain, someone who might not want a visitor. I couldn't do it. He apologizes for waking me. I think a second or two and then thank him: he has given me the chance to be awake ond realize the pain is gone, completely. I look at the clock. 8:00 p.m. What an awful day.

It's good to hear a voice beside me, talking about mundane things. I've never had a sustoined conversation with this man before, and I enjoy it greatly. Hearing a voice, caring what it's saying, feeling no pain and knowing it. It's perfectly lovely. I think now that the voice was mostly my own. I don't think I gave him much chance to respond. Morphine does funny things to the head; I hope he knows that. He does tell me that the mighty Tar Heels won again. I am immensely pleased that they could do it without my rooting for them, but a little disappointed for the same reason. He stays nearly an hour, then leaves, promising to return tomorrow. I savor my poinless state and then call home so everyone else can sleep well, too.

The pain never returns. The IV has filled me with fluid which I pass uneventfully throughout the night. Nurses check for the stone and never find it. I know the pain will be back, but I enjoy its absence greatly. All night I doze, waking for temperature and blood pressure checks periodically. A nurse comments on my low heart rate and blood pressure, asks if I'm a runner. I promise myself to continue aerobics.

In the morning the attending physician returns with a stone expert and an intern. We all decide that I will pass the stone as well at home as in the hospital. They prescribe an antiemetic to take along with the

demerol when the pain returns, and they suggest lots of fluids — beer is the operative word. I'm not much of a beer drinker, but I decide on a sixpack of Bud Light. Their commercials make me laugh out loud; they deserve my money.



For the next several days I fallaw my usual rautine, drinking more than usual, hurting vaquely in the right kidney every now and then, straining my urine in order to see and retrieve the stane when it passes. They want ta analyze it, see what it is made of. On the fallowing Thursday I have o followup appointment in the uralagy clinic. They suggest an intravenous pyelagram, an x-ray dye study of the kidneys, ureters and bladder ta see if the stone is still within. I have that done the next doy and the radiologists nicely offer to review the study with me. No stane. Yippee.

I return for a final followup the next Tuesday. A new attending urologist reviews my case with me. I certainly had a stone. I certainly no langer have a stone. I should drink a lot of water always to keep fluids running through so fast that nathing has a chonce to sit and crystallize. Since my previous stanes were calcium axalate, this one prabably was, tao. Na sense trying to avaid calcium; if that doesn't get me the oxalate will.

This dactor gives me my reasan for writing this account. It's nat that I wont to remember every minute of the episade. It's just that I never knew what

ta da when I got a stone, but now I da.

When my next stone episode begins — if ever it does — I will first take poin medication. Nat demerol, a paar chaice, but dilaudid, for which this physician immediately writes me a prescription. He tells me I con save it until I need it or fill it naw and have the pills handy. I choose the latter. Dilaudid has a very good pain relief profile. Second, I will drink great quantities of fluid to push the stone thraugh my system. And, under the following three circumstances, I will proceed to the nearest emergency room.

- 1. If the pain medicatian cannot control the pain. A body in extreme pain doesn't act naturally. Certain bodily systems stop functioning, and ane in particular leads to the second circumstance under which I will ga to the emergency room.
- 2. If I stort to vomit. When ossaulted by great discomfart, the stomach stops peristalsis, the rhythmic movement by which it processes our faad and drink intake. What the bady then consumes sits in the stamach until it is rejected, and vomiting ensues.

If you can't get fluids to stoy in, you con't get fluids to push the stane out. You need introvenous fluids which bypass the stamach and give the kidneys samething to work on.

3. If I run a fever. Fever means infectian and infection can mean damage to the bladder, ureters ar kidneys. Other measures I dan't want to think obout may be needed. I am glad I anly encountered the first two circumstances.

My father asks me on the telephone to describe the pain. I say immediately that it's as if someone unzipped the skin in back aver my kidney, reached in, took the kidney in his hand and squeezed. It's a deep, dull, definite, nauseating pain. And it stays. I find it interesting now that I used a zipper analogy; I guess I expect another stone.

I am grateful to that young uralogist for orming me with the information I need to deal intelligently with my next stone. I had five years between my first and second stones and eight years between my second ond third. If the progression continues I will have eleven years between my third and faurth. 1997. I con wait.

#### Latchkey Children

Assad Meymandi, M.D.

Latchkey children are an end praduct of a set of camplex social and societal issues which directly stem out of wamen's need to meet their maximum patential autside the hame. It began in the sixties, accelerated in the seventies, and in the mid eighties, according to statistics from the U. S. Bureau of Census, up to 75 percent of mathers are working, earning and contributing to the family income. These statistics reveal same ather interesting phenamena; amang them are the fallowing:

- 1. Middle class, white, anglosaxon, protestant Americans are having fewer and fewer children. Na baby baam far WASPS!
- 2. The same group of Americans is deferring marriage, therefore past-paning bearing children, so that the majority of mothers in that category are an average age of 28.3 years, according to 1984 US Census Bureau.
- 3. The lawer middle closs is bearing the brunt. Because of inflatian and limited incame, bath porents need to wark in arder to make ends meet. This cantrasts sharply with the first graup the so-called YUPPIES yaung professianal peaple wha cansume a tremendaus amaunt of goads by way of expensive automabiles, VCRs, a second home, etc. This third graup has na choice: both parents must work in order ta put the food an the table.

As a result of these few factors amangst many, the problem of latch-key children is an ever growing and an ever encompassing ane. Frankly, epidemialogists and socialogists are at a lass to affer solutions to the problem of latchkey children, simply because the nation has not been

prepared far the unprecedented increase in the numbers of these children.

#### What Does It Mean?

We have begun to collect hard data which suggest very strangly a relatianship between the incidence of latchkey children, adalescent depression, increased sexual activity at an inappropriate and young age, teen suicide and conduct disarder of early adulthoad. Recent studies published in the Journal of Orthopsychiatry, the American Journal of Psychiatry and social work literature suggest that the incidence of delinquency, truancy, teen suicide, teen pregnancy and abartion is 500 percent more in latchkey children than it is in non-latchkey children.

#### **Dynamics**

The most frequent feeling of the latchkey child is a sense of abandonment. The secand mast frequent feeling is that of fear, and the third is sadness and grief. A child needs companianship. All social and behavioral scientists, including socialogists, psychiatrists and psychalogists, agree that na child under age 10 years should be left alone. It is a dongeraus chance to take to leave a child unattended. Many parents rationalize that nothing can happen if they leave their child olone anly two hours a day between 3:30 when he comes hame from school and 5:30 when one af the parents shows up. That is two hours a day, 10 hours a week, 500 haurs a year which is almost 21 days out of the year. This is an unacceptable and exarbitant amount of time for a child to be alone.

#### Consequences

When children ore left alone they

have a tendency ta became marase, argumentative, depressed with a feeling of unwantedness and abandanment that unconsciously and insidiausly tears up the fabric of their psychalagical matrix. Unquestianably these children start experimenting with sex and sexuality at an early age. These children are the target of the tobacca campanies. Accarding to statistics from the Tabacco Institute and the National Cancer Institute (the extreme opposing bodies wha constantly argue about tobacco), about two and a half million teenagers are seduced into smoking every year. Usually the latchkey children are the targets of their advertising. Alsa, the incidence of drug abuse and alcahal abuse is higher amangst these children.

#### What To Do?

Obviously a child shauld not be left alane. Even a bad babysitter ar a bad nursery is better than being left alane. The amount of money spent on child care is worth every penny insuring the child's psychalagical welfore. If you have ta leave your child alane, please provide a pet. Of all pets a dog is the best. Systematic scientific studies prave that dogs pravide a sense of protection, help a child avercame laneliness, pravide companionship and, last but not least, are a reliable ond nan-abusive playmate.

#### **National Solutions**

Recently, the Hause Select Cammittee an Children, Yauth and Families headed by Representative Gearge Miller, a California Demacrat, has come to examine this problem, and recognize the causal relation between latchkey children, mental illness and delinquency. Since March

Fram 1212 Walter Reed Raad, Fayetteville 28304.

1985 the Select Committee has held hearings. It is in the process of develaping legislation to fund research projects to collect more hard data on the subject. It is hoped that ultimately a rational approach will be found to

provide wages for working mothers to stay home and care for their children at least before age 10. We might find a solution to the enormous problems of mentally ill youth through prevention. I will apprise you of the

congressional development as the work progresses. In the meantime, hug your family and try not to leove your children unattended, especially before age 10!

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#### **EDITORIAL**

### **DRGitis**

John R. Gamble, Jr., M.D.

In this world of instant communication and computer facility it becomes obvious that we should use both liberally, and thus alleviate many cases of frustration and even terminal despair. Each day takes many physicians deeper into the labyrinth of trying to understand what is needed to justify an admission or a procedure or even the proper diagnosis in a multi-system illness — or when does a symptom qualify as a diagnosis.

There seem to be two reasonably simple solutions to at least a part of this dilemma that I think we should try. They are:

1. A computer console at every dictating station that would be programmed for several video instructive aids. The physician could type in his tentative diagnosis and the following information would appear: (A) peer review criteria for such a diagnosis, plus the peer review criteria for admission; (B) necessary components of the admitting orders; (C) list of necessary (confirmatory) information that must be contained in the past and/or present history, physical examination, and laboratory/x-ray type data along with this would be a model scenario for these sections; (D) lists of tests or procedures that are considered acceptable or necessary, as well as a list of non-authorized tests and procedures; (E) the DRG days allowable for this diagnosis along with any influencing factors; (F) a breakdown of the disease criteria that explains which symptom or finding or combination of them is necessary to satisfy the diagnosis; (G) a diagnostic flowsheet of examinations; (H) criteria to be met for in-patient treatment versus outpatient treatment; (I) any guidelines about this illness as to reporting of admissions to governmental or private insurance carriers with telephone numbers, i.e., preadmission approvals, etc.

2. An arrangement whereby an authorized local physician would act as a consultant for emergency room cases that seem to need admission when the attending is unsure of his judgment insofar as it might satisfy peer review. If no such local physician is authorized or available at the time, provide a telephone number of a staff peer review physician.

What better projects for the North Carolina Medical Society to undertake for physicians than these? They can secure capable professionals and computer programmers and software producers to make this program available to hospitals and physicians, selling it at cost or even a profit. I feel that the North Carolina Hospital Association would assist in the program development. A quality program could have a national market. The contents of the program would be an extremely valuable medical educational tool.

The availability of an authorized physician consultant representing peer review would certainly simplify decision making with emergency admissions. The good and reasonable offices of the North Carolina Medical Society requesting this cooperation should certainly be viewed favorably.

The computer age is here for our use and benefit.

From Box 250, Lincolnton 28092.

#### THE LUCK OF THE DRAW

## Data Terminal Operator Aces the Doctors

Claude S. Burton, M.D.

Suffering with an enigmatic chronic illness, an elderly woman was admitted to our hospital. Her condition was characterized by worsening malnutrition and "failure to thrive." Referring and admitting doctors found no obvious reason for her loss of appetite and loss of weight. She was recently widowed and chronic depression appeared to be the likely cause of her problems. Still endocrinopathy, malabsorption, occult malignancy and organic brain syndromes were to be excluded. In the midst of an exhaustive yet nonenlightening evaluation the woman became febrile, then hypotensive, presumably due to Gramnegative sepsis from a urinary tract infection. Indeed, she responded well to antibiotics and fluids in the intensive

From the Division of Dermatology, Duke University Medical Center,

care unit. Our intensive care unit was no smarter than her previous doctors at diagnosing the underlying process.

On the third MICU day 1 was stunned on rounds to see the diagnosis printed on a computerized slip and stapled to her flow sheet: "Order 0018 — urine cytology — malignant cells suspicious for adenocarcinoma!" I was flabbergasted. Who deserved credit for such clinical acumen? Curiously, no one admitted ordering the test. Subsequent testing confirmed the diagnosis.

Inspection of the chart revealed the answer to the mystery. Order 0018 was written "urine culture and sensitivity." On our hospital computer system, available tests are displayed on a screen and selected by touching a light pen to the screen. "Urine cytology" appears immediately below "urine culture" and had been selected by accident. The Data Terminal Operator had made the diagnosis!





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# Addison's Disease: The Right Doctor in the Right Place

Harry T. McPherson, M.D.

PATIENTS need a little luck, namely the right doctor in the right place. In 1954 our patient, then a 50-year-old housewife from Wilmington, became progressively ill with weakness, anorexia, weight loss and ultimately confusion. Her doctors, appreciating the severity of her illness, wished to send her to Duke Hospital. In her delirium auditory hallucinations appeared, and she refused to be moved until the voices could be quieted. Eventually her external auditory canals were plugged with cotton and she was transferred to the Duke Psychiatry Service.

The psychiatrists were puzzled by her illness and their inability to communicate with her. The deafness seemed a major problem, so an orderly was summoned to take her to the Otolaryngology Clinic. The orderly, only recently hired, mistakenly took her to the Ophthalmology Clinic where she lay strapped to her stretcher. Dr. Frank Engel, a distinguished endocrinologist, had ordered a new pair of glasses and on that morning dropped by to pick them up in the Ophthalmology Clinic. Spotting our lady who had hyperpigmentation characteristic of Addison's disease, he recognized the presence of a medical emergency and followed her back immediately to Meyer Ward on the Psychiatry Service. There he quickly demonstrated that she had additional features of Addison's disease: cachexia, buccal mucosal pigmentation, profound orthostatic hypotension, hyponatremia and hyperkalemia. Prompt treatment with parenteral steroids was life saving.

Our patient remained under Dr. Engel's care until his

From the Division of Endocrinology, Duke University Medical Center, Durham 27710.

death in 1963 since which time I have followed her. She is now 81 years old and enjoys a full life at her home in Wilmington and summer home in the mountains. She takes Cortisone acetate 25 mg in the morning and 12.5 mg in the evening, supplemented by the mineralocorticoid, fludrocortisone, in doses varying from 0.05 mg daily to 0.05 mg every third day. In times of stress she doubles her Cortisone quickly and indeed is most expert in the care of Addison's disease. It has been interesting to note that while she presented with delirium in adrenocortical insufficiency, she also becomes disoriented and very excited at times when receiving larger doses of parenteral steroids to cover a stressful illness. Through the years she has been hospitalized seven more times: one with Addisonian crisis, three with urinary tract infections, one for diagnostic workup of what proved to be a mediastinal fat pad, one for surgical removal of an epidermoid cyst of the thigh and one for a cataract extraction. With aging she has developed very mild hypertension, osteoporosis, a colon polyp, cataracts and occasionally the pain of angina. On December 4, 1985 she looked well, had normal complete blood count with differential, normal electrolytes, creatinine and sugar, a normal electrocardiogram, and a chest x-ray showing only osteopenia and a tortuous aorta.

Many times we physicians look but don't really see. Here Dr. Engel saw, acted with speed and saved a life for more than 31 years. Yes a delirious patient with a lot of pigmentation and a little luck adds one more to the legends of Dr. Frank L. Engel. See and hear — emulate his example!

THE LUCK OF THE DRAW

# Let's Listen to the Patient: A Story of Heart Failure from Cystic Carcinoid Tumors

Jerome M. Feldman, M.D.

A black lady, aged 43, was seen at Duke Medical Center on March 12, 1980 with the story and findings of congestive heart failure. Her liver had been enlarged for at least six years. Examination by ultrasonography revealed an enlarged right ventricle and multiple cysts in the liver. The largest cyst was approximately 11 cm in diameter and was situated in the right lobe of the liver near the right hemidiaphragm. A liver biopsy showed fibrous tissue. Urine HIAA was increased as was the serum serotonin.

Eventually, careful questions brought out most of the features of the carcinoid syndrome. These included flushing spells precipitated by alcohol, spells of hypotension,

From the Division of Metabolic, Endocrine and Genetic Diseases, Duke University Medical Center, Durham 27710.

deepened facial creases and disease of the tricuspid and pulmonic valves. The atypical finding was the avascular cysts.

The doctors were fascinated by the liver findings and pathology and were all for treating the tumor and its manifestations. The lady would have none of it. She said, "I can't walk, I can't rest, I'm short of breath, I swell. That means my heart is sick. Leave my liver alone. Fix my heart or let me go home."

On August 26, 1981, one year five months and fourteen days after she was first seen at Duke, the surgeons granted her request. The tricuspid valve was replaced and the stenosed pulmonary valves were opened. All of the signs of congestive failure promptly disappeared, and the patient is enjoying life in Wilson.

Sometimes it pays to listen to the patient.

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# Early Blood Grouping and Transfusion in North Carolina: Contributions of Laurence H. Snyder

Paul J. Schmidt, M.D.

THE Carolinas have a history of introduction of blood transfusion during the last half of the nineteenth century. The transition from bloodletting! to blood transfusion already was taking place.<sup>2</sup> Direct transfusion of human blood was well recorded.<sup>3</sup> Of course there were no sterile containers, no anticoagulants, no science of immunohematology and no ABO grouping and no crossmatching. However, most patients on whom transfusion was attempted were ready to die anyway from their basic problem. Since the chances of a random blood donor being ABO compatible are at least six out of ten, for most exsanguinating patients some blood was better than no blood.

The scientific basis for blood grouping was described in Vienna by Karl Landsteiner at the opening of the twentieth century. Although he did his work in 1900, the application to transfusion was not made until ten years after that. Surgeons had been transfusing for a hundred years and were not likely to look to a laboratory doctor for help on such a physical mode of therapy.

Some movement for scientific change came with the introduction of sodium citrate as an anticoagulant in 1914. No longer was it necessary for the surgeon to be on the scene to pump blood directly from donor to recipient.<sup>4</sup> Blood could now be taken from the donor and stored, and there would be time in which to do some serologic testing between donor and recipient.

#### North Carolina State College — 1923

The stage was set by the early 1920s for North Carolina to become one of the first states to benefit from that knowledge of the blood groups. Eugene Brooks, the State Superintendent of Public Instruction, became the fifth president of the North Carolina State College of Agriculture and Engineering, now North Carolina State University, in June of 1923. He had promised a broad program to make State College an outstanding technological school. The reorganization program came at the right time in a state ready to move with the sociological and technical needs of the Twenties. Brooks had the support of the faculty and the alumni. Cooperative degree programs were developed in a new School of Science and Business, and graduate instruction was offered.

Among the first of the new faculty hired in 1923 was

a young man only 22 years of age, Laurence Hasbrouck Snyder, only later to become known as the "Father of Human Genetics" (figure 1). He was fresh from college at Rutgers with a bachelor's degree in Zoology and was enrolled in the Graduate School at Harvard. Those credentials got him a job as Instructor at the revitalizing State College. The young instructor taught Animal Morphology, Embryology and Ornithology but the emerging awareness of the human blood groups intrigued him. He choose blood grouping as his graduate study field as part of a larger interest in genetics.



Figure 1: Laurence H. Snyder at North Carolina State College, 1925

From Box 2125, Tampa, FL 33601.



Figure 2: Zoology Building at North Carolina State College, 1930.

#### Genetics and Blood Groups

Almost as soon as Snyder came to Raleigh, he began one of his first projects; he was contacted by William Allan from Charlotte, who had been collecting pedigrees from a number of evidently hereditary conditions. Allan was not sure how to deal with his data, so Snyder and Allan sat down together and formulated some relevant procedures. They became close friends. Allan was very well acquainted with the people of Western North Carolina, and he took Snyder to many large family reunions in the mountain regions in order to observe the effects of genetic transmission.

Snyder collected hundreds of blood samples in North Carolina, recording data on race and family group. The histories traced a number of heritable conditions and also provided compelling additional support for the Bernstein hypothesis of a single locus for the ABO blood group genes. These studies added to the ever-increasing knowledge of the distribution of the blood groups.

In another project Snyder spent some time on the Cherokee Indian reservation. He wanted to substantiate an assumption that racial crossing would actually bring about changes in the blood group frequencies of the populations concerned. By calculating gene frequencies from the data he collected, he found that pure blooded Cherokees had very low frequencies of the genes resulting in the antigens A and B, and a very high frequency of the gene that does

not produce either antigen and results in group O. He was able to work out a continuum from pure-blooded Indians through mixed-blooded individuals to Caucasians.

Snyder's report was one of the few available on American Indians from the Southeastern part of the United States for many years. Later, more blood factors were discovered including the Diego of the American Indian. When further testing was done in the Cherokee thirty-five years later, 7 Snyder's findings were confirmed.

His pioneering work in human genetics was recognized early and the American Medical Association sponsored the 26-year-old graduate student to speak at the International Eugenics Conference in Holland in 1927. His work at State College (figure 2) allowed him to develop as well his interest in birds, and he prepared a 47-page guide to "Common Birds of North Carolina Farms, Gardens and Orchards" for the North Carolina Extension Service.

A major outcome of Snyder's years in North Carolina was his book, "Blood Grouping in Relation to Clinical and Legal Medicine," published in 1929. That book was solicited by Williams and Wilkins following the publication of a number of outstanding articles and a requested editorial on blood tests for paternity in the *Journal of the American Medical Association*. There were only three other books on blood groups and transfusion published by Americans before 1930. Available copies of Snyder's monograph are extremely rare.

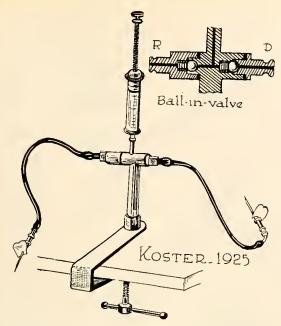


Figure 3: Koster apparatus for direct donor-to-patient transfusion.

#### Blood Transfusion Techniques — Medical Qualifications

The 1929 book contains chapters on the history, the indications and the methods for transfusion and gives a marvelous picture of the armamentarium of the transfusionist of 60 years ago. Florence Seibert had not yet done her work on bacterial pyrogens, and the sterile citrate solutions of 1923 produced high posttransfusion fevers. As a result, direct transfusion from vein to vein by syringe pump and stopcock was still a preferred method. In a description of the choices for the direct transfusion apparatus, Snyder pictures the Koster apparatus (figure 3) which, he says, "I have used and found satisfactory."

When Snyder sent me his book and I read those lines I questioned the propriety of a young zoology student with no formal medical training performing transfusion, even if he was from Harvard and it was only 1925 in then rural North Carolina. Snyder's reply in correspondence dated September 1981 was as follows: "In preparing for the writing of the book, I realized that some discussion of transfusion would have to be included. Therefore I asked my physician friends to let me watch transfusions and to learn all I could about them. They kindly let me watch, and even to assist on occasion. But I never did any transfusions by myself. They were all under the strict supervision of physicians, who did the actual work."

In William McLendon's writings on medical practice and medical education in North Carolina, he tells us that many North Carolina physicians before the War Between the States received their education by apprenticing or "reading Medicine" under the tutelage of some practicing physician. <sup>10</sup> But evidently that was still true a hundred years later. There were a number of pioneers among Snyder's physician friends. In our continuing correspondence Snyder wrote in June 1984 of what he called a "vignette of trivia": "When I first reached Raleigh, N.C. in 1923, I was helped in my work by various physicians, to whom I will always be grateful. . . . I noted that there were in active practice a number of physicians, highly respected and capable doctors, who had earned their professional standing and their right to practice by apprenticeship, but who themselves had not actual M.D. degrees."

#### Medical Genetics and the Educational Triangle

In 1926, during his tenure at North Carolina State, Snyder completed the degree of Doctor of Science from Harvard University. Four years later, he was invited to Ohio State University. There he became the first Professor of Medical Genetics in the United States and taught the first required course in medical genetics at any medical school in the country. His landmark book, *The Principles of Heredity*, was published in 1935 and went into five editions over the next 20 years. A quarter of a million copies were sold. Everybody in several generations learned genetics from Synder.

In 1940 at the request of the Dean of the Duke University Medical School, the Carnegie Corporation supplied funds for Snyder to return to North Carolina as a visiting lecturer in medical genetics. The grant provided for the presentation of 15 weeks of lectures, not only at Duke where he was headquartered, but also at the medical schools of Wake Forest and the University of North Carolina. While he was in Durham, the planning for the forthcoming move of Wake Forest Medical School to the Bowman Gray School of Medicine was already under way. The prospective dean of the new school asked him for suggestions and Snyder recommended the establishment of a Department of Medical Genetics as an innovative step. That was accepted and Snyder's friend from his first post in Raleigh, William Allan, was appointed Chairman of the first such department in the country.

Upon completion of the Carnegie lectures, the series was published in 1941 by the Duke University Press as a well-illustrated book, one of the best early texts in the field.<sup>11</sup>

#### Rh Nomenclature

Later, when Snyder was Dean of the Graduate College at the University of Oklahoma, Surgeon General Thomas Parran of the United States Public Health Service appointed him chairman of an advisory review board to recommend the names for the various anti-Rh sera the Public Health Service was about to license. The other members of the Board were W.B. Castle of Harvard (a son of the Castle with whom Snyder had taken his doctorate) and Max N. Wintrobe of Salt Lake City.

There were two different systems of Rh nomenclature, one proposed by A.S. Wiener in the United States and the other by R.A. Fisher and R.R. Race in Great Britain. Each had developed violent proponents. The scientific literature was divided and there was considerable confusion for the readers. The review board was charged with rec-

ommending a system to label Rh typing sera for use in pretransfusion testing, where confusion could not be allowed. The problem of ABO nomenclature and the interchange of numbers by Moss and Jansky was too recent.

The review board held a public meeting in Washington on October 20 and 21, 1947, listening to statements and arguments of acrimony and bitterness over the differing philosophies. The board decided that the users of the reagents would be served best by placing the nomenclatures of both systems on the labels, with the Wiener notations first, followed by the Fisher-Race notations in parentheses. 12 The Snyder report was accepted by the Public Health Service and its recommendations were in place for many years until reversed after the death of Wiener in 1976.

#### 1986

Laurence Snyder's gifts to the discipline of human genetics are many and are well remembered and recorded;6 this report is only a special note on his pioneering work in blood group genetics. His practical observations and interests fueled scientific interest in transfusion not only in North Carolina but throughout the world. His career has ranged as well from boogie-woogie piano to civil rights and East-West relations and he has been the recipient of many awards, honorary lectureships and degrees. 13 From 1958 to 1962 he was the President of the University of Hawaii where Snyder Hall houses research projects in the health sciences. At the time of this writing he resides in well-earned retirement with Guldborg Herland Snyder, who became his wife a few short months after he began his long career in North Carolina 63 years ago.

North Carolina's contributions to transfusion medicine continued after Snyder. John Elliott, who introduced the practical use of plasma for World War II, did his pioneer work in Salisbury in the early thirties. Some have called

him the founder of the first "blood bank" fifty years ago.14 A great number of blood banking activities continued during and after World War II and into the post-war period evolving into the advanced transfusion practice of today. The whole story of the evolution of modern transfusion medicine can be pictured in the course of the 63 years in North Carolina since Laurence Snyder came in 1923.

#### Acknowledgments

Thanks are due to Maurice S. Toler, Archivist, North Carolina State University, Raleigh for the information on North Carolina State College and the use of figure 1 from the University Archives.

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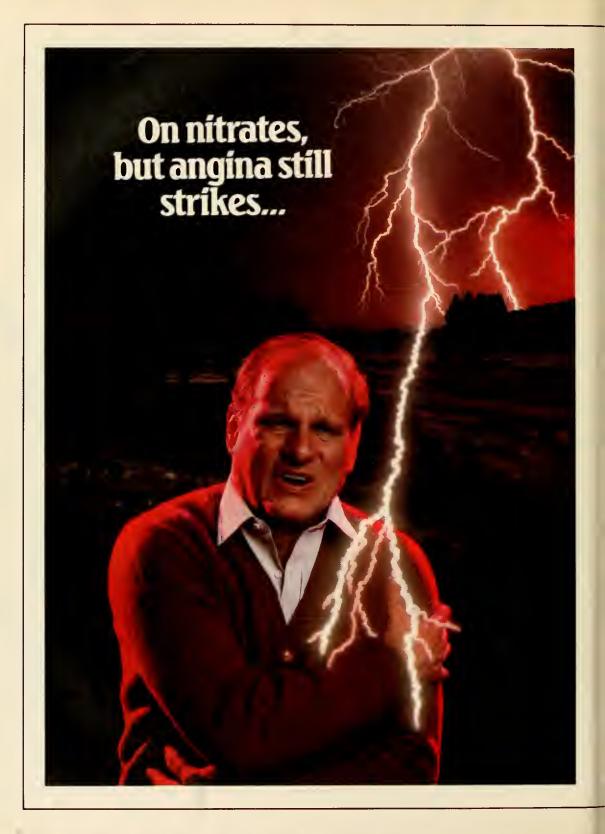
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Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment, however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil therapy. Patients with atrial flutter or fibrillation and an accessory AV pathway (e.g. W.P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN Because of verapamil's effect on AV conduction and the SA node, 1° AV block Because of verapamil's effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. Marked 1° or progressive 2° or 3° AV block requires a dosage reduction or, rafely, discontinuation and institution of appropriate therapy depending upon the clinical situation. Patients with hypertrophic cardiomyopathy (IHSS) received verapamil in doses up to 720 mg/day. It must be appreciated that this group of patients had a serious disease with a high mortallty rate and that most were refractory or intolerant to propranolol. A variety of serious adverse effects were seen in this group of patients including sinus bradycardia, 2º AV block, sinus arrest, pulmonary edema and/or severe hypotension. Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued. Precautions: ISOPTIN should be given cautiously to natients with impaired benatic function (in covere defining the incomposition). to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients. with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. Combined therapy with ISOPTIN and proprianolol should usually be avoided in patients with AV conduction abnormalities and/or depressed left ventricular function. Chronic ISOPTIN treatment increases serum digoxin levels by 50% to 70% during the first week of therapy, which can result in digitalis toxicity. The digoxin dose should be reduced when ISOPTIN is given, and the patients should be carefully monitored to avoid over or under-digitalization. ISOPTIN may have an additive effect on lowering blood pressure in patients receiving oral antihypertensive agents. Disopyramide should not be given within 48 hours before or 24 hours after ISOPTIN administration. Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPIIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate anigest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames test. Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. Adverse Reactions: Hypotension (2.9%), peripheral edema (1.7%), AV block 3rd degree (0.8%), bradycardia. HR < So/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported (See Warnings.) The following reactions reported in less than 0.5% occurred. (See Warnings.) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation **How Supplied**: ISOPTIN (verapamil HCI) is supplied in round, scored, film-coated tablets containing either 80 mg or 120 mg of verapamil hydrochlonde and embossed with "ISOPTIN 80" or "ISOPTIN 120" on one side and with "KNOLL" on the reverse side. Revised August, 1984



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## Teaching Alcoholism and Substance Abuse: A Medical Malfeasance?

Sherwood W. Barefoot, M.D.

A LCOHOL and its problems have been around as long as history has been recorded. Today, some feel we are more likely to be destroyed by it than by nuclear hazards. Speaking recently, former governor and U.S. Senator Harold Hughes stated that American society could probably empty half the jail and prison cells in the country by coming to grips with the addiction problem.

In 1922, an effort began to abolish alcohol. After a decade of failure, the emphasis was on control. This has been tried for fifty years and the problem is still with us.

Should we actually expect a workable solution with such a dichotomy of concepts — unable to live without versus trying to live with? The frailties of man and the magnitude of the problem suggest that our best option is, in some way, to try to adjust<sup>2</sup> rather than strive to abolish or control.

Approximately two hundred years ago, Dr. Benjamin Rush called alcohol abuse a disease. The medical profession did not officially endorse this concept until November 1956 when the AMA House of Delegates issued a statement recognizing alcoholism as an illness. In 1968, Congress passed the Alcoholic Rehabilitation Act and the following year established the National Institute on Alcohol Abuse and Alcoholism.<sup>3</sup> Alcoholism had become legally defined and labeled a treatable disease.

Completely neglected, the alcoholics themselves had in 1935 developed their own program of recovery which they called Alcoholics Anonymous (AA). Using well-defined principles, called steps, one alcoholic helps another by sharing experience, strength and hope. This Fellowship now has a world-wide membership of millions and is responsible for the sobriety of hundreds of thousands.

#### Present Status of Knowledge and Teaching

A recent polling of physicians by the Center for Health Policy Research<sup>5</sup> revealed that respondents almost unanimously believed alcoholism to be a disease and a major national problem, but only 27% felt competent to treat such patients. Despite the fact that alcoholism follows only heart disease, cancer and stroke as a leading cause of death,<sup>2</sup> Pokorny and Solomon found in their 1983 survey of 35 randomly selected medical schools that the hours devoted to teaching alcoholism and substance abuse constituted about 1% of total teaching hours.<sup>6</sup> Conversations with present medical students and recent graduates suggest this is probably representative of the teaching of alcoholism and substance abuse in most medical schools. For this

state of affairs, there are possible explanations, but none are acceptable. The medical profession is, indeed, guilty of having failed in a public trust.

of having failed in a public trust.

Of all "incurable" diseases, alcoholism can be most effectively controlled. Permanent remission lasts as long as there is total abstinence. The basic tenet of recovery is for the alcoholic to free himself from the obsession to drink.

#### North Carolina Medical Schools

A summary of instruction available in identifying and treating alcoholism and substance abuse was requested from the deans of the four medical schools. One did not respond to three separate requests. Information received from the other three is shown in table 1. All the schools, of course, offer excellent instruction in the pharmacology, physiology, biochemistry and pathology of alcohol and other mind-altering drugs.

#### Recognition and Treatment

Alcoholism, in the early stages, is often most difficult to detect. Fifty years ago, when confronted with diagnostic problems, we were told to consider syphilis and tuberculosis as possible etiologies. Good advice today would be to consider alcoholism and substance abuse as a possible explanation for often quixotic symptoms since it is the great masquerader of our time. A modicum of understanding of the personalities and character traits of alcoholics may be gained by reading such descriptions by Marty Mann<sup>7</sup> based on astute observations in a broad experience in the field of alcoholism.

An alcoholic's drinking history is worthless since denial is the hallmark of the disease. Ewing<sup>8</sup> suggests that the CAGE (Cutting down, Annoyance by criticism, Guilty feelings, and Eye-openers) questionnaire be a routine part of every history. Gamma glutamyl transpeptidase serum determinations, the best of blood tests, detected only one-third of persons consuming more than 16 "drinks" per day or those clinically diagnosed as alcoholics while the CAGE interviews identified nine of ten alcoholics and detected 93% of excess drinkers.<sup>9</sup>

Details of performing the CAGE Questionnaire consist of the following questions:

Have you ever felt you ought to Cut down on your drinking?

Have people Annoyed you by criticizing your drinking? Have you ever felt Guilty about your drinking?

Table 1
Available Recognition and Treatment Instruction

School	Nature of effort	Availability	Hours	Clinical experience		
Wake Forest	Drug Abuse (second year) Includes physicians' role in recognition & treatment	Basic Curriculum	4	Students attend one AA Meeting		
	Seminars in Substance Abuse (third year) Basic concept and clinical application	Basic	8	Attend at least one AA Meeting		
	Alcoholism Training Program in Family Medicine (third year)	Elective	Approx. 12	Three hours in alcoholism detox center. Encounters with alcoholics on both in-patient and out-patient basis.		
Duke	No formal program "May be two or three lectures in required curriculum."					
East Carolina University	No response to three separate requests to dean's office.					
UNC-CH	No structured program. In process of tendencies among medical students		am as well as or	ne which might help recognize incipient		

Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hangover (Eye-opener)?

Experience indicates that one positive answer calls for investigation; two may suggest incipient trouble and the individual should be counseled regarding the progressive nature of alcoholism; and three affirmative answers totally eliminate the non-alcoholics.

Once the alcoholic has been identified, knowledge of two basic principles will suffice in the management of this elusive disease:

- Avoid prescribing other mind-altering substances as a substitute for alcohol. To do so may lead to a second addiction. During withdrawal, the judicious use of a drug of the nature of diazepam may be indicated along with phenytoin to lessen the likelihood of seizures.
- II. Refer the individual to AA. An alcoholic physician author has described AA as "the nation's best specialist in alcoholism." The physician would do well to make the acquaintance of a mature member of AA who has several years of sobriety. He will gladly deal with referred alcohol problems and be grateful for the opportunity to "carry the message."

Most alcoholics are able to find sobriety in AA but some need to begin recovery in a reputable treatment facility. A knowledgeable member of AA can identify those who need in-patient care. Aftercare should include vigorous and regular involvement in AA. With such a regimen, treatment facilities may experience a recovery rate (measured by complete abstinence from alcohol for one year following treatment) of at least 75%.

#### Getting Alcoholics and Substance Abusers to Treatment

Few individuals with alcoholism and substance abuse seek treatment of their own volition before reaching their so-called "bottom." Denial is often most difficult to overcome

Intervention<sup>12</sup> is a process designed to overcome denial and enable the alcoholic to recognize his need for help.

A scenario, usually using relatives and friends as actors, is developed which might cause the alcoholism and substance abuse sufferer to comprehend his predicament. Every effort is made to reflect understanding and compassion without infringing on his dignity. For most, this approach produces better results than frank confrontation; but if not successful, the latter may be advisable.

#### **Suggested Programs**

The ideal person for developing and conducting an alcoholism and substance abuse program for medical students and house staff members is one who has experienced both the horrors of alcoholism followed by recovery and the frustrations of getting a medical education. He is in a position to evaluate what he believes might have been helpful to him had it been available at that time in his life. Seldom is such a staff member available to assume these extra duties. In some instances, consideration might be given to using a qualified outside recovering alcoholic physician with a part time clinical appointment. The Chairman of the Impaired Physician Committee of the North Carolina Medical Society, from time to time, might know of recovering qualified physicians. In any case, in developing an alcoholism and substance abuse program, it would be helpful to recommend disenfranchisement of all members of the Curriculum Committee who consider alcoholism to be evidence of moral inadequacy.

Regardless of who is available to begin an alcoholism and substance abuse program, a helpful one may be developed by emphasizing certain basic principles and using knowledge of members from the AA community. Remember that the primary care physician sees more patients with alcoholism and substance abuse (mostly unrecognized) than with any other disease.

#### Medical School Curriculum

To be offered in the third or fourth year — (sequence is important):

 One two-hour session: Audio-visual "Disease Concept of Alcoholism II" (37 minutes) followed by discussion. (Available from Gray Whiteaker Co., 615 S. Belt West, Belleville, IL 62221 — cost in June 1985 was \$600.00.)

- Three one-hour sessions with talks by different members from the AA community, the first dealing with the 12 steps of AA; and two with different speakers recounting what it was like, what happened, and what it is like now.
- 3. One two-hour session in small groups to evaluate and discuss impact of previous sessions. (AA members would be appropriate moderators.)
- 4. One two-hour session: Audio-visual "The Prescription Trap" (40 minutes) followed by discussion. (Available from same source as #1 at cost of \$310.00 as of January 1984.)
- One one-hour session: Summation of recognition of alcoholism and substance abuse (including CAGE Questionnaire, JAMA 1985;252:1905-7) and Intervention and Alcoholism (Southern Med J 1985;78:1333-4).

#### Other Aids:

Attending at least three AA meetings during the year instruction is offered in addition to reading the following:

- 1. Alcoholics Anonymous<sup>13</sup>
- 2. New Primer on Alcoholism7
- 3. I'll Quit Tomorrow<sup>14</sup>

#### Post Doctoral Program

Residents in primary care programs would spend a minimum of one week in a reputable alcoholism and substance abuse treatment facility. This learning experience should be available to trainees in all disciplines on an elective basis. These residents would be involved in detoxification, intermediate therapy (individual counseling, group discussions, didactic lectures and audio-visuals), family therapy and after-care during this tour; and should be required to attend an AA meeting each night during the week.

#### Other Sources for Program Development

A very limited number of medical schools have pioneered programs for teaching alcoholism and substance abuse. Dartmouth Medical School established a program in 1977 with a grant from the Operation Cork Program of the Joan B. Kroe Foundation. Trevor Price, M.D. is the present director. At Rush Medical School, Thomas Dent,

M.D. is director of the alcohol education course.<sup>15</sup> These sources might offer valuable help in planning a program. Robert Niven, director of the National Institute on Alcohol Abuse and Alcoholism encourages and will help with curriculum development for medical schools.<sup>15</sup>

#### Summary

Despite the fact that alcoholism, with all its lethal effects, ranks as the fourth most frequent cause of death in our population, only about 1% of total teaching hours in medical schools nationally is devoted to its recognition and treatment. Three out of four physicians feel that they are expected to swim in deep water without having had lessons when it comes to treating patients with alcoholism and substance abuse.

Lack of understanding and failure to disseminate available knowledge of this subject (especially as developed by AA) is a failure on the part of medical educators to respond to the needs of society. Since this is, indeed, a failure in a public trust, it must be viewed as a medical malfeasance.

#### Acknowledgment

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#### MODERN MEDICINE

#### ASAP's Fables

Francis A. Neelon, M.D.

THE U.S.A. is a society awash with acronyms. How I often do we hear something "is SNAFU" or that the report is "needed ASAP." Perhaps it's not surprising then that acronyms abound in medical charts. I do not know whether there are more now than in the past, but it is certain that their presence makes it difficult for the uninitiated to read and understand medical records. For instance, it took me a while to realize that no vital signs were available on a patient I recently saw because she was "OOP" (Out On Pass). At times even the context does not give a clue as to the meaning. On such occasions the ordinary mortal will ask a nurse or house officer the meaning of "BLMG" or "BLMLS." The response is usually one of polite disdain or condescending explication, as though the questioner had suddenly fallen to earth from another planet or was mentally slow. When medspeakers are asked what they mean by a string of unintelligible initials, they usually only repeat the acronym, slowly and in a loud voice. I have seen medical record forms that request writers to "Use No Abbreviations" ("U.N.A." for short) but neither that or any other tactic to date has stemmed the flooding tide of cryptic initials. Most observers bemoan this trend.

Recently it has occurred to me that acronymania has come about because it serves an important social purpose. The ability to understand and to use acronymolaliac utterances can distinguish the true believers from the heathen; it is the badge of belonging. There is nothing new about this use of language — the Gileadites used "Shibboleth"

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to detect and slay the fugitive Ephraimites who could not pronounce the word (Judges 12:6) and American Gls were supposed to have detected German infiltrators by asking them to say, "Which way went the wicked whipoorwill," or to tell "Who played second base for the Brooklyn Dodgers in '32." As proof of this function of medical abbreviations, 1 provide the three vignettes below, constructed for test purposes from abbreviations common in our medical charts although none appeared in precisely the present form. The fact is that our medical personnel (at least some of them) can read and understand these sentences and translate them into sensible English. If you cannot, then you are no member of my tribe, maybe not even a member of my nation.

- 1. An elderly diabetic man who had PNH and NPH was treated with NPH and doing well, awaiting NHP, when he was recognized by the PHN to have HNP.
- 2. While working on the mss for her M.S., young Ms with MS and MS developed an altered MS after an injection of MS.
- 3. A psychiatric patient with difficulties in LOC was given LOC when he was hospitalized after an episode of LOC.

Considering the value of such touchstones in exposing imposters on the hospital floors, 1 offer the following thoughts:

- 1. Acronymophobia is no virtue.
- 2. Acronymophilia is no vice.
- 3. Whenever possible: Get OOB, ASAP!

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erythematesus has been reported with thiazide diuretics
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### 1985 — The Year of the End User: Computer Data Viewed As a Strategic Resource

Joseph J. Kroger

Twas the best of times, it was the worst of times... "By now, that quote from Dickens' Tale of Two Cities is old hat. But, looking back over the computer industry's experience in 1985, it's also irresistible. Because rarely has a 12-month period been so replete with both promise and frustration.

Promise, because giant developmental strides were made toward the next generation of computers. And frustration, because many companies were shaken by a worldwide slump in both hardware and software, along with a dramatic drop in demand for semiconductor chips.

The reasons for those sluggish sales deserve exploration. But first, let's review some of the year's more positive highlights.

America's love affair with electronic gadgetry continued unabated. Consumers snapped up videocassette recorders (VCRs) at a rate of more than 45,000 a day during the hectic weeks before Christmas and, by year's end, had purchased over 12 million of them (compared to about seven-and-a-half million in 1984).

Another commodity that seemed to be on everybody's gift list was the digital laser compact disc player, that amazing little box which reproduces sound with incredible clarity and threatens the demise of the turntable.

Still other "hot" items aimed at the home market included a camera that boasts two computer chips in its body and one in each lens, so that it can set exposures and focus by itself... a desk blotter featuring a calculator and an alarm clock plus a telephone with a memory that stores 112 phone numbers and a digital readout to show how long you're talking!... and a 28-inch-tall robot, priced between \$400 and \$500, that can be programmed to follow a prescribed behavior pattern for up to seven days.

But the real innovations — and there were many of them — had little to do with fun and games.

Scientists and engineers at numerous research centers around the country achieved startling advances in efforts to make silicon chips and nerve cells 'talk' to each other. Encouraged by preliminary successes researchers envision a 'human-meets-machine revolution' in which tiny computers implanted in the nervous system could restore functions damaged by disease or injury. Within five years,

according to one estimate, researchers may achieve a crude implant in the nerve of a human arm or leg.

That's not at all farfetched — especially in light of one of the year's most heartwarming developments: the perfection of a voice activated wheelchair which, by responding to 19 separate commands, brought mobility to previously helpless quadriplegics. In addition, advances in computer technology may eventually restore partial hearing to the deaf . . enable the blind to regain at least some vision . . and allow stroke victims to regain and control movement of their limbs.

Feats such as chip implants depend upon making electronic components as small and fast as possible. That technology, too, took a huge leap forward last February when several manufacturers announced memory chips capable of storing over a million bits of information. Measuring a mere one centimeter by half a centimeter, the new chips can access data over ten million times a second.

Remarkable though that seems, it's a snail's pace compared to the speed of a new communications system which actually shuttles data back and forth along as much as 30 miles of fiber-optic cable at the unprecedented rate of 275 million bits per second.

Advances in software — many of them utilizing down-to-earth applications stemming from research in the burgeoning field of artificial intelligence (Al) — also made headlines. Computer Integrated Manufacturing (CIM), which is aimed at increasing both efficiency and productivity, became a common phrase in the jargon of the work-place. Before actually implementing an automated factory, design engineers used specially devised programs to simulate plant layouts on a computer. One such AI system, called "Just-In-Time Manufacturing," shows real promise as a means to reduce costs and improve quality by virtually eliminating the need for inventory and storage.

Still other innovations involved breakthroughs in the areas of parallel processing (in which computer programs for more than one run are stored simultaneously and executed concurrently) and the packaging of integrated circuits (many transistors connected into microminiature circuits, all on a very small scale). The list goes on and on

Why then, with new developments occurring at breakneck speed and sophisticated electronic products spilling out of every nook and cranny of the marketplace, did the

From the President and Chief Operating Officer, Sperry Corporation, Box 500, Blue Bell, PA 19424.

computer industry experience a slowdown in 1985?

Part of the answer — the easy part — is that market analysts were overly optimistic. But that's *too* easy.

Another, more important part lies in the simple fact that many buyers found themselves confronted with an embarrassment of riches. Consequently, they did what smart end users invariably do when faced with a confusing array of choices: they stopped buying and stood back to take a hard look at the situation.

What they saw — particularly those in business and industry — was a problem. A big problem. For years, they'd been on a buying spree. Afraid of being left behind, they'd purchased practically every new product offered — regardless of who made it or who serviced it. And now too many of them were stuck with a hodgepodge of expensive equipment that couldn't work in concert.

Suddenly, they didn't want just another new product. They wanted solutions. Balanced solutions providing maximum integration of products. Solutions offering maximum systems compatibility . . . integration . . . convergence. Solutions that protect their computer investments — and deliver increased productivity and cost-effectiveness.

The computer industry swallowed hard. And then it faced up to the inevitable conclusion: It could no longer afford to be product-driven. Instead, the industry had to become *customer*-driven. It had to offer solutions that are integrated to protect and reinforce near-term investments.

It had to happen. Once personal computers proliferated, end users within a given organization discovered that they all had to share the same data base. From there, it was easy to determine that, unless all their company's computers could communicate with each other, they weren't getting an adequate return on their investment.

Not only that, but senior executives began viewing data as not just a set of files, but rather as a *strategic resource* that, managed properly, could give the company a competitive edge. In other words, management was no longer willing to spend data processing budgets merely to save money. Instead, they expected such outlays to *make* money.

No wonder, then, that last year saw a rush on the part of the computer industry's main players to provide their biggest customers — those in business, industry and government — with communications-based integrated information systems. And, because no single company can possibly possess all the solutions, it's not surprising that almost every day brought news of alliances and partnerships.

What we're seeing now . . . and will continue to see for the next several years . . . is the emergence of a handful of world-class players. They're players who are going after enormous stakes. But they're also players who — unlike their counterparts prior to 1985 — recognize that . . . to survive . . . the rules of the game are set not by themselves, but by the customers whose problems they must solve.

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Julie Marianna Thomas (STUDENT), L-7 Royal Park, Carrboro 27510

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Charles Leon Branch, Jr. (RESIDENT), 315 Janet St., Winston-Salem 27104

John F. Butterworth, IV (AN). 300 S. Hawthorne Rd., Winston-Salem 27103

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#### LEE

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#### MCDOWELL

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David Nels Ugland (OPH), 100 Queens Rd., Charlotte 28204

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Susan Downer Foreman (PD), 505 Bremerton Dr., Greenville

Eric Martin Humphreys (IM), ECU School of Medicine, Greenville 27834

Edward Kenneth Katz (P), ECU School of Medicine, Greenville

Thomas Brenton McElwee (GS), Dept. of Surgery, ECU School of Medicine, Greenville 27834

Claire Virginia Cooper (P), 6512 Six Forks Rd., Ste. 505, Raleigh 27609

Robert Thomas Harris (IM), 2800 Blue Ridge Rd., Ste. 503, Raleigh 27607

Charles Henry Hicks (CD), 3400 Executive Dr., Raleigh 27609 Thomas Wilbur Maddox (GS), 3814 Browning Place, Raleigh

#### **Continuing Medical** Education

Please note: 1. The Continuing Medical Education Programs at Bowman Gray, Duke, East Carolina and UNC Schools of Medicine, Dorothea Dix, and Burroughs Wellcome Company are accredited by the American Medical Association. Therefore CME programs sponsored or cosponsored by these schools automatically qualify for AMA Category I credit toward the AMA's Physician Recognition Award, and for North Carolina Medical Society Category A credit. Where AAFP credit has been obtained, this also is indicated.

#### IN STATE

#### April 14-June 6

Postgraduate Course in Medical Ultrasound

Winston-Salem

Dr. Frederick W. Kremkau, Center for Medical Ultrasound, Info: Bowman Gray, Winson-Salem 27103. 919/748-4505

#### April 16

Cholecystitis, Cholelithiasis, Cholecystectomy

Place: Sanford

Info: Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

#### April 17

Anaerobe Symposium Place: Greenville

Credit:

6 hours Category I AMA Office of CME, ECU, Box 7224, Greenville 27835-7224. 919/ 758-5200, ext. 208 Info:

#### April 20-23

Administrative Skills II: Planning Change and Conflict Resolution

Place: Rougemont Credit:

20 hours Category I AMA, AAFP Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-Info: ham 27710. 919/684-6878

#### April 22-26

Infection Control Workshop

Place: Chapel Hill

35 hours Category I AMA W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118

#### April 25-26

Pediatric Springfest in Charlotte

Place: Charlotte

Credit:

Department of Pediatrics, Charlotte Memorial Hospital, Box 32861, Charlotte 28232. 704/338-3156

#### April 28-May 2

Radiology Review Course 1986

Place: Durham

Credit: 42 hours Category I AMA

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710, 919/684-6878

#### May 1-2

Biotechnology Symposium: Progress in Endocrinology-Regulatory Proteins and Their Receptors

Greenville

8.5 hours Category I AMA Credit:

Office of CME, ECU, Box 7224, Greenville 27835-7224. 919/ 758-5200, ext. 208

#### May 8-9

Advanced Cardiac Life Support

Chapel Hill Place:

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118

#### May 15-17

Philosophy of Medicine Series

Chapel Hill

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118

#### May 15-17

Pediatric Rehabilitation Workshop

Place:

Chapel Hill W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill Info: 27514. 919/962-2118

#### May 16-17

Annual Autism Conference

Place. Chapel Hill

10 hours Category I AMA Credit:

Fee:

\$100 W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118 Info:

#### May 17

Neoplastic Hematopathology Conference

Place: Greenville

Credit: 6 hours Category J AMA

\$55 Fee:

Info: Office of CME, ECU, Box 7224, Greenville 27835-7224. 919/ 758-5200, ext. 2108

#### May 21

Polypharmacy/Drug Interactions

Place: Sanford

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

#### May 23-24

Pediatric Infectious Diseases of the Lung and Gut

Place: Durham Credit: 10 hours Category 1 AMA

Fee:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 Info:

#### May 28-30

Sea Level Invitational Conference on Geriatric Medicine

Place: Sea Level

Office of CME, ECU, Box 7224, Greenville 27835-7224. 919/ Info: 758-5200, ext. 208

What's New in the Treatment of Cardiovascular Disease

Durham Place:

Credit: 6 hours Category I AMA

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 Info:

June 3

Duke Tuesday Place: Durham

Credit: 5 hours Category I AMA

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

June 6-7

Cardiology Scientific Session and Alumni Reunion

Place:

Chapel Hill W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118 Info:

June 7

Short Course in Diagnostic Imaging: Body II

Place: Durham

8 hours Category I AMA Credit:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 Info:

June 8-13

Fellowships in Family Medicine

Place: Chapel Hill

Credit:

100 hours Category I AMA W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill Info: 27514. 919/962-2118

June 12-14

33rd Annual Mountaintop Medical Assembly

Place: Waynesville

Info: Debbie Ford, 37 Miami Drive, Waynesville 28786. 704/452-

June 18

What's New and Old in GI Disease

Place: Sanford

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

June 19-21

Seaboard Medical Association of North Carolina and Virginia Annual Session

Place: Kill Devil Hills

Info: Julian R. Taylor, M.D., Box 10387, Raleigh 27605, 919/821-2226

June 27-28

Contact Lenses and Refractive Surgery: What Is the Balance?

Place: Wrightsville Beach

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

ham 27710. 919/684-6878

July 7-11

28th Annual Postgraduate Course/Morehead Symposium

Place: Atlantic Beach

Credit:

26 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878 Info:

July 9-22

Reconstructive and Cosmetic Surgery

Place: Durham

Credit: 25 hours Category I AMA

Linda Mace, Box 3707 DUMC, Durham 27710. 919/684-8111 Info:

July 16

Cost of Medical Care

Place: Sanford

Info: Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330, 919/774-6518

July 23-August I

9th Annual Radiology Postgraduate Course

Place: Atlantic Beach

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 Info:

OUT OF STATE

April 24-26

Sky-Top Meeting on the Treatment of Depression

Place:

Scottsdale, AZ Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-Info:

ham 27710. 919/684-6878

April 25-27

Radiology Review 1986 Place: Hilton Head, SC

Fee: \$350

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514, 919/962-2118 Info:

May 15-18

Annual Meeting, The Virginia Society of Otolaryngology-HNS Place: Wintergreen, VA

Donna Strawderman, 4205 Dover Road, Richmond, VA 23221.

804/353-2721

May 21-24

Eighth Annual Evoked Potential Symposium

Hilton Head Island, SC Credit:

30 hours Category 1 AMA

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

May 29-June 1

Annual Meeting, The Virginia Society of Ophthalmology Place: Norfolk, VA

Donna Strawderman, 4205 Dover Road, Richmond, VA 23221. Info: 804/353-2721

June 11-14

Dermatology for Non-Dermatologists Place: Myrtle Beach, SC Credit: 15.5 hours Category I AMA

Fee: \$350

Info: Division of Dermatology, Box 3135 DUMC, Durham 27710.

919/684-2504

June 19-22

Annual Duke Conference: Contemporary Developments in Anesthesiol-

ogy Place: Hilton Head Island, SC

Credit:

17 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878 Info:

June 24-29

Second Annual Advances in Internal Medicine

Hilton Head Island, SC 16 hours Category I AMA Place:

Credit:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

June 30-July 5

Midsummer Family Practice Digest Place: Myrtle Beach,

Credit: 30 hours AAFP

Info: Mary Anna Hendley, NC Academy of Family Physicians, Box

20146, Raleigh 27619. 919/781-6467

July 16-20

Seminar on Preventive Medicine: Nutrition Place:

Hilton Head Island, So Credit:

12 hours Category I AMA Harold D. Schutte, 53 S. French Broad, Asheville 28801. 704/ Info:

258-0969

July 29-30

Advanced Neurosonology Seminar
Place: Snowmass, CO
Info: Frederick Kremkau, M.D., Bowman Gray School of Medicine,

Winston-Salem 27103, 919/748-4505 July 31-August 2

Advanced Applied Ultrasound in Obstetrics

Place:

Snowmass, CO Snowmass, CO Frederick Kremkau, M.D., Bowman Gray School of Medicine, Winston-Salem 27103. 919/748-4505

September 11-13

Doppler Echocardiography Seminar Place: Tarpon Springs, FL

14 hours Category I AMA Credit:

Fee:

Frederick Kremkau, M.D., Bowman Gray School of Medicine, Info:

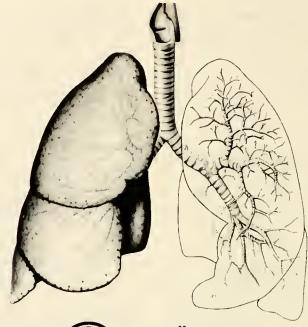
Winston-Salem 27103, 919/748-4505

October 17

Selected Topics in Pediatrics
Place: Norfolk, VA
Info: Jean E. Shelton, M.D., 800 West Olney Road, Norfolk, VA

23507. 804/628-7179

### Consider the causative organisms...



## cefacior

### 250-mg Pulvules t.i.d.

#### offers effectiveness against the major causes of bacterial bronchitis

H. influenzae, H. influenzae, S. pneumoniae, S. pyogenes (ampicillin-susceptible) (ampicillin-susceptible)

Brief Summary Consult the package therature for prescribing information

intornation and Usage Cector\* (cetacler Lilly) is indicated in the treatment of the following infections when caused by susceptible strains of the designated micrographisms. Lower (espiratory infections) including pneumona caused by Streptococcus pneumoniae (Diplococus pneumoniae) Maemoph—ilos influenzae and S. properes (group A beta hemolytic

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Note: Cector\* (cetaclor Lilly) is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to pencifellin allergic patients. Pencifellin is the usual drug of cheice in the freatment and prevention of streptococal infections, including the prophylaxis of rheumatic fever See prescribing information.

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#### Letters to the Editor

Ivan W. Brown, M.D.

#### To the Editor:

January 31, 1986, was a singular day in the history of the Watson Clinic and the Lakeland Regional Medical Center. On that day a remarkable scientist, a remarkable physician, a remarkable man made his last exit from the stage of the "Watson Clinic Playhouse." That man is Ivan W. Brown, M.D.

There is to my knowledge only one person in the Clinic who has known Ivan longer than 1 . . . Jack Collins. Jack left Duke before Ivan had "matured," so I guess 1 know what he has contributed to the "big picture of medicine" better than anyone else in town. 1, therefore, consider it my responsibility, indeed my privilege, to tell you something about the texture of this remarkable man.

After graduating from the University of Rochester in 1936, he matriculated through Duke University School of Medicine and graduated in 1940. Rather than entering directly into a surgical residency, which had always been his goal, he spent six months as an assistant in physiology and then two full years of House Staff training in Pathology. This was followed by over two years during the Great War in the European Theater of Operation. He was with the 65th General Hospital of the U.S. Army. That was the famed Duke Unit. Ivan has served as the Historian of that unit. The outstanding scientific accomplishments that he made during that period in Europe have been glossed over in the history that has been recorded by Ivan. But it was with that unit, doing research at Oxford and elsewhere in England on the side, that Ivan made contributions to the technology of blood procurement and storage that saved many lives during the war and are even today still of importance. He was recognized nationally in 1952 for his research in low temperature blood preservation.

Speaking of blood, did you know that Ivan was in: 1948-1949 Assistant Director, National Blood Program,

American Red Cross

1949-1950 Consultant, National Blood Program, American Red Cross

1953-1962 Member, National Research Council on Blood and Related Problems

1951-1964 Consultant to the Commission on Plasma Fractionation, Harvard University

1960-1966 Associate Editor of the Journal TRANSFU-SION

Coming back from the War, Ivan completed with distinction three years of general surgical residency. He was then awarded a five year Markle Scholarship in Medical Science (1948-1953). In those days, competition for such an award was fierce. A Markle Scholar was considered the highest recognition that a young scientist could attain. It meant not just one year or two years, but five years of clinical investigation.

It was in 1950 that I first met Ivan, but it was not until 1954 that I really got to know him. He talked as long then as now and with as much enthusiasm. He smoked as much then as now, the only difference was that I smoked with

him in those days. [One of my great failures is that Ivan continues to smoke.] At that time, I labored through my cardiovascular Fellowship, and Ivan carried on his research on the side as he completed with distinction the thoracic surgical residency.

By 1956, he had attained his general surgical and thoracic boards and Dr. Daryl Hart, Chairman of the Department of Surgery at Duke, was wise enough to let Ivan do what he liked to do most . . . biological research.

Ivan knew most of the leaders of the field personally, not just in this country but throughout the world. From 1965 to 1972 he was a member of the Executive Committee of the Division of Medical Sciences of the National Research Council. He was a member of the first National Research Delegation to visit the Soviet Union at the opening of the Cultural Exchange of 1957. He brought back to this country the first stapling instrument, which was developed for use in patients by a Russian scientist. It was about that time that he developed the first practical heat exchanger for the heart-lung machine that made open heart surgery safer for longer procedures. That contribution was recognized in 1980 by the American Society of Mechanical Engineers by the award of the distinguished National Landmark in Mechanical Engineering Award.

In our laboratory at Duke, he showed us how to elucidate the cause of the subendocardial hemorrhages that were always present in patients who died after cardiopulmonary bypass surgery and what's more he figured out how to prevent them.

He was the pioneer in introducing hyperbaric oxygenation to the American medical scene in the late 1950s and early 1960s. I was privileged to go with him to England, Scotland, the Netherlands and Sweden during those days for the purpose of learning the potential capability of hyperbaric oxygenation. I was impressed on that trip how all of the leaders . . . the giants . . . of the international cardiovascular field knew Ivan Brown and sought him out to listen to his wisdom.

It was Ivan Brown who was responsible for the hyperbaric program that was so scientifically productive at Duke University. It was Ivan Brown who made possible the present "Man Under the Sea" program that is so productive currently at Duke. During the hyperbaric era, the enthusiasts thought it was the answer to all cardiovascular problems. We used it for strokes . . . for arrhythmias . . for gas gangrene, etc. But Ivan was always somewhat skeptical. He wanted facts, not just anecdotes. I guess it was from Ivan that I learned the importance of the saying, "It is not just a question of 'Can you?' . . . but the more important question of 'Should you?'"

Because he was first and foremost a scientist, he was Chairman for the National Research Council on Hyperbaric Oxygenation from 1965 to 1968, and the President of the Third International Congress on Hyperbaric Medicine

It was during the sixties that he was a frequent commuter to Washington as a Consultant to the Executive Office of the President of the United States, as a member of the Surgical Study Section of the National Institutes of Health, a member of the National Research Council Committee on Naval Medical Research, and a member of the Joint USA-USSR Committee on Health Cooperation in Cardiovascular Diseases.

For these and many many more contributions, in 1965 Ivan W. Brown, Jr., [if my mind serves me correctly] was the first faculty member of the Medical School to be awarded a James B. Duke Distinguished Professorship.

Although I knew Ivan well in the laboratory, I knew him best as a physician and a surgeon. He kept patients with heart block alive for months to years with epicardial electrodes leading out through the skin to external pacemakers before the days Bill Chardack miniaturized the pacemaker so that it could be placed under the skin. He was the first physician south of the Mason-Dixon line, if my recollection is correct, to totally implant a pacemaker under the skin. Never have 1 known a surgeon who workedup his patient as carefully before the operation and followed the patient as carefully after the procedure as Ivan Brown. I watched him implant the first Starr-Edwards aortic valve prosthesis at Duke University. He did it in my patient, and then ten more of my patients, until we finally felt comfortable with the procedure and demonstrated that the patient lived longer with the surgery than without it.

Ivan was and still is a perfectionist and it is probably for that reason he is considered by many somewhat of a loner. If you look for Ivan in the doctors' lounge, where most of the "physician conversation" goes on, you will never find him. He has always had little time for "small talk." He was always on the wards. Through the years I have realized that Ivan has gained the distinction of being a doctor's surgeon, and what greater recognition could one have?

Because Ivan felt so compelled to take care of people, he left Duke in 1968 and joined the Watson Clinic. I hate to see him step down now, for although I have listened to his stories for thirty-six years, and I have rarely heard him repeat one, I am sure that he has many more stories that I have never heard that would be as fascinating as those that I have. Never once have I heard him tell stories about "I did this" or "I did that." He never thought it was important for anyone to know when he had done a hundred of this or a hundred of that.

On January 31, 1986, a giant of a man of medicine stepped down from the medical scene . . . and so few who pass him in the corridors of the hospital and in the streets of the city know what a giant of a man he has been. But those of us who do know him know that the leaders of the cardiovascular field of today can see so much further because they stand on the shoulders of the giant . . . Ivan W. Brown, Jr.

Henry D. McIntosh, M.D. Watson Clinic Lakeland, FL 33802

#### Marital Therapy

#### To the Editor:

Dr. James R. Wright of Raleigh has given me a copy of the article, "Why Marital Therapy?" by Linda Rubin,

which was printed in the January 1986 issue of your publication (NCMJ 1986;47:25-30). I write to inquire if copies of that article are available for purchase; if they are not, where may permission be sought for the duplication for presentation to those who come to this office for such counsellings.

The article has much to commend it, but I do not want to abuse any copyright protection or to use without permission from the publisher and author. Thank you for your coursel

> Albert G. Edwards The First Presbyterian Church 112 South Salisbury Street Raleigh 27601

We are always happy to have our published articles put to good use and are especially pleased when our permission is sought.

#### Where You Stand Determines What You See: Blue Cross/Blue Shield

#### To the Editor:

I congratulate you for your efforts to educate our patients about the changes that are taking place in the medical care system in our State. The topic of "Hospital Utilization in North Carolina" in the Features for Patients, February 1986, by Dr. Sandra Greene and Dr. Bill DeMaria, was excellent in its preparation and timely in its presentation. The physicians in North Carolina and the Blue Cross/Blue Shield Corporation of North Carolina (BC/BS) deserve the credit for the rapid decrease in hospital utilization that has occurred in the three years discussed in the article. The BC/BS Corporation and the physicians in our State cooperated in the rapid utilization of ambulatory surgery and office surgery. Preadmission certification, implemented first in areas of high utilization, caused large decreases in hospital admissions, and the initial objection by some physicians has moderated.

I am concerned about the time and energy that is being consumed by members of the North Carolina Medical Society because of their anger towards this North Carolina insurance company. Members are writing resolutions regarding the Medical Society's future relationship with the BC/BS Corporation of North Carolina, and discussing the future of one of the hardest working committees of the North Carolina Medical Society. We can use our time and energy better.

Let's look back. A position on the Committee on Blue Shield was sought after only a few years ago. The Committee served our patients by evaluating new procedures, discouraging ineffective ones, and prior to FTC threats protected patients from excessive fees. How many other North Carolina insurance companies have contributed time, personnel, and money to provide a forum for us to review reimbursement problems with our peers?

The Blue Cross/Blue Shield Corporation of North Carolina was the leader in establishing ambulatory surgery. They did not apply second opinion surgery to the entire State, and they are now providing health care coverage to patients who have been denied health insurance previously. They were the first company to reimburse physi-

cians for the most important part of diabetes care, diabetes education, in accordance with the standards proposed by the National Diabetes Advisory Board. Very few other insurance carriers in our State have done this! The Blue Cross/Blue Shield Corporation of North Carolina played an important role in the establishment of the Mecklenburg County Health Care Cost Management Council, which has become a model for physicians becoming involved in the containment of health care costs.

The Blue Cross/Blue Shield Corporation of North Carolina is a business. They have, like we do, a bottom line. This company has lost business because of the rapid trend of businesses in North Carolina to become self-insured for their employees' health care expenses. Examples of this are the state employees of North Carolina, Burroughs Wellcome Corporation, and many others. The Blue Cross/Blue Shield Corporation of North Carolina, as a business, responds to what its customers request in health care coverage. It, along with many other insurance companies in North Carolina, is becoming a health care provider and, on the other hand, many of our members are now in the health insurance business. The truth is, we are now competing with a corporation that in the past was part of our team as we provided health care to our patients.

Changes in the way we practice and the way we are reimbursed will come so rapidly that we may feel overwhelmed and angry, but let's not lose our objectivity. If we can't be friends, then let's acknowledge that we are now competitors and wish a fellow nonprofit North Carolina corporation well and use our resources and energy to a better advantage. We have much to do!

There are many issues that deserve our attention. How do we successfully compete with organizations that are experienced in the health insurance business? What is the right amount of utilization of health services? What is too much care for the terminally ill? How do we continue to provide the right care to all in this era of great cost shifting? How do we deal with the ethical dilemma of choosing the best care for our patients when the costs that we render may well decrease our income rather than increase it? These are hard questions that we should begin immediately to discuss and give our attention to. The answers to these questions should be with the medical profession and not our patients' insurance carriers, legislators, personnel officers, etc.

William W. Fore, M.D. Greenville, NC 27834-4354

#### To the Editor:

Those of us who find Blue Cross's recent Costwise advertising on television offensive can certainly turn off the television. When we see the same ads in our *North Carolina Medical Journal* we can likewise turn the page. However, I would ask: is the financial compensation great enough to run an ad which you must know is distasteful to so many of your readers?

George J. Miller, M.D. 1207 Highland Drive Washington 27889 "A soft answer turns away wrath." Sooner or later you will be an editor. Blessings on you.

#### Where You Stand Determines What You See: MRNC

#### To the Editor:

No one can fault Dr. Bryan's aggravation with the medical review routine here in North Carolina (NCMJ 1986;47:97).

However, it could be much worse in the fact except that organized medicine, particularly through the alert and earnest activities of the North Carolina Medical Society, has kept this within the bounds of the medical profession. It is up to us now as physicians to obtain the data, to see how these things operate, and in time to bring about sufficient influence, if that be needed, to change the law. It is only if the people who become upset with all this get to their elected representatives in Washington that anything will be done.

The alternative is to have a system such as is present in England and to a large extent also in Canada, where the state has already made a lot of arbitrary decisions so that the physician becomes the servant of the state and carries out the activities prescribed for him. Such, for example, is the case in England where dialysis at the cost of the state is not available to anyone over 55 years of age. This is not an ethical problem in England since the physician simply does not have this type of therapy available to his patients no matter how deserving.

Eben Alexander, Jr., M.D. Bowman Gray School of Medicine Winston-Salem 27103

#### To the Editor:

After reading the February issue's letter (NCMJ 1986;47:97) from Dr. James A. Bryan, II regarding peer review, Medical Review of North Carolina, Inc., HCFA and the prospective payment law, I concluded that Dr. Bryan would have done well to have attended the physicians' information session for physician consultant reviewers of Medical Review of North Carolina, Inc. in Raleigh December 4. He would have heard again how the review process works and perhaps not conveyed the erroneous information contained in his February letter to the Journal regarding how the physician peer review system works. I use the word "again" because I personally have communicated in a detailed letter to Dr. Bryan how the review process of Medical Review of North Carolina tries to give each physician as much appeal process for his case as Public Law 98-21 allows.

First, Dr. Bryan has not comprehended that there are no admission "guidelines" or criteria sets sent down from the Health Care Financing Administration. The screening criteria that are used by the reviewers in determining whether a case should be referred to a physician consultant for review were adopted and modified by the review committee and MRNC board of directors — all actively practicing physicians who, like all the physician consultants employed by Medical Review of North Carolina, are subject to the same review procedures. These criteria sets are under constant review and revision with the goal of making

them effectively screen out the cases that require review by a physician. Since PRO review began in North Carolina, approximately 85% of all admission records reviewed have been approved by this initial screening.

Second, Dr. Bryan would have heard again that, although responsibility for documentation of medical necessity and appropriateness of care rests with the attending physician, MRNC requests its reviewing physician to use only his best medical judgment in making decisions, to disregard the criteria sets in making a determination, to allow "ties" to go to the attending physician, and ultimately to explain in as much detail as possible the clinical reasons for his approval or denial of a case. Getting the physician consultants to explain adequately these medical reasons remains a problem in that frequently not enough explanation accompanies the decision. A "denial" does not occur until after the attending physician and/or hospital has had an opportunity to add further information not already contained in the medical record either by letter or, if the physician chooses, by phone during which time the physician consultant reviewer does not remain anonymous. (Did Dr. Bryan call and confront his reviewer with new information not contained in the medical records of his denied or reviewed cases?) Approximately 15% of the time an attending physician responds to a "predenial notice" with a phone call in addition to a letter. There is in the law presently no provision for physician or hospital appeal beyond the reconsideration level. In North Carolina 5% of all reviewed cases have been denied initially with 40% of these denials "overturned" on reconsideration, leaving an overall denial rate of 3%, which is the current national average denial rate for the peer review program.

Third, Dr. Bryan would have learned that Medical Review of North Carolina, Inc. has received from HCFA no "quotas" for denial rates, demands for criteria changes, or "savings" to be made in "disallowed" hospital admissions. The MRNC board determined the initial contract objectives' numeral targets, and will do so again when another contract is negotiated.

Fourth, Dr. Bryan would have learned that the current emphasis from the Health Care Financing Administration is on trying to assure quality of care rather than reducing costs. I cannot believe that the peer review system is making Dr. Bryan change his practice "style of care" from one of patient advocacy and quality care to one of being a "servant/advocate of the system." As a North Carolina taxpayer, I would hope that he is teaching his medical student and house staff charges that quality of care does not necessarily mean hospitalization in most cases and that quality is often better served with outpatient care. There is a widely held and trumpeted assumption that the prospective payment system has thus far seriously compromised the quality of medical care for Medicare beneficiaries. HCFA's emphasis during the next contract period will be on seeing whether this is true and, if so, charging the PROs to develop methods to ensure that this does not occur.

Congress and the Reagan administration at this point must think that the prospective payment system and peer review are cost effective in that the program still exists and will continue to exist even if Dr. Bryan achieves his goal of "disbanding MRNC." While Dr. Bryan decries the financial experience of his hospital under prospective payment reimbursement, hospitals in general seem to have prospered, and a neighboring academic hospital representative wrote recently in their publication of the hospital's Medicare reimbursement having increased by 4% under prospective payment. Without question most physicians would rather have no review. However, as Dr. John Wennberg pointed out to the Medical Society recently, we physicians had better be in the business of determining what is right and proper quality medical care, how much care the population needs, where it should occur, what outcome standards should be, and lead the way in helping to make the societal decisions regarding the "rationing" of expensive treatments and operative procedures that produce marginal results. If physicians don't make these decisions or at least have major input in them, whom would Dr. Bryan have do it and perform the "peer review" required in the prospective payment law? Given the fact that both public and private review of medical care is here to stay, I would rather have my medical judgments scrutinized by one or more physician "Monday morning quarterbacks." Whom would Dr. Bryan have do it? There likely will be "regional" PROs in HCFA's next contract period in that outside states are bidding for review contracts of those states now without peer review organizations. Having "peer" physicians from neighboring states review my work would incite me to join in Dr. Bryan's ventures. As a medical educator Dr. Bryan would better serve the taxpayers, his patients, his students, and his peers by using his talents in helping to develop peer review methodology that is more efficient, consistent and equitable and that ensures quality medical care. The largest burden of the development of diagnostic and therapeutic techniques rightfully falls to medical educators. Likewise, they should be in the forefront of the development and the teaching of compassionate, caring, quality and, yes, cost efficient medicine.

If the majority of physicians in North Carolina feel as Dr. Bryan about Medical Review of North Carolina then it cannot and will not survive. Nor should it. I'm sure that there are many non-physician bureaucrats who would love to have us fail what Senator Durenberger has termed the "physicians' last chance" of physician-directed peer review. There is still in the law the opportunity for any physician-sponsored organization to bid for and possibly obtain the Medicare review contract. If the state Medical Society or other physician-controlled organization doesn't have this contract, eventually private review organizations, fiscal intermediaries, or insurance companies will get the chance to bid. Personally, I'd rather have as many physician members and as many different physician reviewers as possible in any review organization looking at my work. I hope that North Carolina physicians can work together to ensure that all patients receive the finest quality of medical care for whatever resources are available.

Donald K. Wallace, M.D. President Medical Review of North Carolina, Inc. P.O. Box 519 Pinehurst 28374

#### A New Chinese Restaurant Syndrome in Your Fortune Cookie

One night recently, I had a flash of insight that has helped me deal with the fun and games of the present hospital practice of medicine. I think that if we look at the hospital as a large Chinese restaurant, it is perfectly understandable what is happening to us doctors.

The day the revelation came to me, I sat in one of our department of medicine meetings in the morning and heard two striking things. One, we medical types had not been good enough yet to meet our Medicare criteria for admitting patients and had not been complying with the severity of illness and intensity of service guidelines that have been handed down from on low.

Two, our surgical colleagues were being asked to rethink (how many times has it been now, since the days of Fleming's discovery of penicillin?) how they would prescribe prophylactic antibiotics, to be sure to meet certain cost containment guidelines.

I sat there and listened to those two matters and felt uneasy, but the pressures of the practice day did not allow my thoughts to gel until that evening.

After I got home and had a chance to put my feet up, there must have been a little boost to my cerebral circulation and then the flash came, like a firecracker. Why did I not think of it before?

All we have to do is realize that the days of ordering the specialties of the house (our hospitals) for our patients may be gone forever and we will have to settle for the family dinners. As you recall, with the family dinners, for a cheaper price, you must choose two items from column A and one from column B. Or is it the other way around?

I can hardly wait for the surgeons and us medical doctors to be issued our menu books. Somehow, I feel they will be rice paper backed, surely not leather bound. For surgical patients who need prophylactic antibiotics pre op, two choices in column A (a penicillin or cephalosporin) and one from column B (aminoglycoside) will be permitted. The prices per ampule will be clearly marked.

For those of us trying to get a very ill medical patient into the hospital by pre admission pleading, the menu we will have in our pockets will outline in column A what severity of illness criteria will impress the admission review coordinators, and in column B we will decide what treatments will be given and at what intensity.

In this Year of the Tiger, then, I was convinced I had it made and was all set to comply with the system and continue to practice good medicine as well.

The very next morning an elderly Peking duck appeared in my office, cold and miserable and thoroughly soaked from a winter rain. I determined from his sodden feathers and other classic physical signs that he was suffering from a severe oil gland blockage.

Sad to relate, this did not meet criteria and I could not get him admitted, even though I was calling for the admission twenty-four hours in advance. Tonight, I may think of a way. . . .

Donald D. Neish, M.D. 2609 N. Duke St. Durham 27704

#### A Lawyer Talks About Malpractice Insurance

#### To the Editor:

As an attorney practicing frequently in the medical negligence area of the law, I can't help but comment upon Dr. Milton D. Quigless, Jr.'s comment in his letter to Thomas Rose, President of Blue Cross/Blue Shield as contained in the December edition of the North Carolina Medical Journal (1985;46:681). Dr. Quigless maintains that for physicians the "greatest economic worry is the malpractice insurance crisis which threatens to erode our financial positions as physicians to a far greater extent than inflation." I don't believe that he can support this statement with the facts. We in this area do wish that the physicians in this state would get together and demand justification from their insurance carriers for the huge increases in malpractice insurance premiums.

Most of the statistics with which I am familiar do not support the notion that there is a malpractice insurance crisis in this state. The one party to this controversy which has thus far escaped close scrutiny is the insurance industry with its accounting practices which result in deceptive estimates of losses. These projected losses are highly inflated but provide the basis for large increases in premiums for the physicians. The projected losses are "later" adjusted downward to reflect actual losses, usually years later and long after the sting of the premium payment for that particular year has worn off.

The insurance companies are supposedly in a "risk" business, but they are very successful in doing away with virtually all risk through their accounting practices. They make a fuss out of a rare loss in one area for a particular year, but who will question them about the billions and billions they usually make? They want to eliminate all risk and pit the physicians against the lawyers in order to evade scrutiny.

I am certainly not an expert on the subject, but I would invite each of the members of the North Carolina Medical Society to give close scrutiny to the insurance industry and the accounting practices they use to justify increased premiums. More often than not, I believe, you will find that premium and investment income has exceeded payouts on claims made. Perhaps the physicians in North Carolina should do as the physicians in California did, i.e., recover hundreds of millions of dollars from their insurance carriers for excessive malpractice insurance premiums.

John Michael Winesette 705 First Citizens Bank Building Fayetteville 28302

#### Dr. Quigless Replies:

#### To the Editor:

I support my statement that "... the greatest economic worry (for physicians) is the malpractice insurance crisis which threatens to erode our financial positions as physicians to a far greater extent than inflation ..." with several FACTS.

First, a good friend of mine who is an OB/GYN specialist in Raleigh tells me that when he started his practice in 1973 his malpractice premium was \$2700. By 1981 this premium had risen to \$5000. In 1985 it was \$11,600 and

in 1986 the premium is \$18,000. The fact is that malpractice premiums for my friend are rising faster than any of his other business expenses.

Second, premium and investment income for a malpractice insurance carrier must exceed payouts or claims made as the carrier spends thousands of dollars on each case successfully defended. Whereas the malpractice carrier defending the doctor wins 83% of cases, payouts on claims made occur in only 17% of cases. This would imply that Attorney Winesette fails to take into account the thousands of dollars spent in successfully defended cases where there is no payout. These thousands mostly go into the pockets of attorneys. Of course, other thousands go to management of the insurance carrier who has to see to matters such as salaries and purchase or rental of office space.

Third, if the malpractice insurance business is so lucrative for these companies, why did *all* of the carriers pull out of the state in the middle 70s, forcing the doctors to establish their own company — Medical Mutual Insurance Company? Why would the doctors, having established this company, then penalize themselves unnecessarily by exorbitantly raising their own premiums?

My friend, the OB/GYN specialist, is insured by Medical Mutual. In *FACT*, the consequence of this rise in malpractice insurance costs has forced my friend to no longer accept Medicaid patients for obstetrical care, as the payment by Medicaid for this care does not cover the insurance cost per case.

Fourth, Attorney Winsette should note that as of 1/3/86, Saint Paul no longer is writing policies for new doctors opening practices in our state. With this news we now have gone beyond the crisis of cost of coverage. We are now once again at the crisis of availability.

Judging from his response to my letter, 1 rest assured that Attorney Winesette is not an expert on the subject of malpractice insurance. The *FACT* is that I question either his intelligence or his integrity.

I invite Attorney Winesette into open public debate on the issue of medical malpractice financing anytime anyplace. He will be made to realize that medical malpractice has evolved from a crisis of cost to the crisis of availability of medical services. Doctors would fear to practice medicine in the present litigious environment without malpractice insurance coverage. Most people consider medical care to be an essential service. Just how essential are lawyers?

Milton D. Quigless, Jr., MD Box 14445 Raleigh 27620

#### Internecine Skirmishes

#### To the Editor:

Dr. Jeffrey Margolis sounds as though he has the soul of a family physician locked in the body of an internist! (NCMJ 1986;47:45) I sincerely apologize to him and any similar souls for any suggestion of stereotype or melodrama. Our colleagues in general internal medicine tend to be our closest cousins and it was surely unintentional if I offended any of them. I intended to draw clearly areas of research involving broader disciplines and to encourage research that demonstrates this kind of thinking.

Attitudes are powerful forces. We must ask ourselves why we choose a certain part of medicine for our careers. Some of my student friends chose internal medicine to avoid pelvic exams, delivering babies, tending to children, and constant encounter with neurotics. Others chose internal medicine to avoid being second class citizens and still have the opportunity to indulge their intellectual curiosity. I usually find my internist colleagues to be most intellectually inquisitive. I would like to encourage my family practice colleagues to do likewise and to utilize the special characteristics of our chosen nitch in medicine that will enable us to contribute significantly to the understanding of disease processes. It is my strong suspicion that if family medicine had already done this the recent trials and tribulations of the Family Practice Department at Duke University would have been avoided.

John R. Dykers, Jr., M.D. Box 565 Siler City 27344

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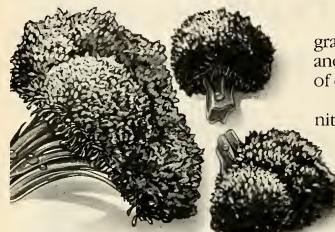
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Jamil A. Fayez, M.D. page 259



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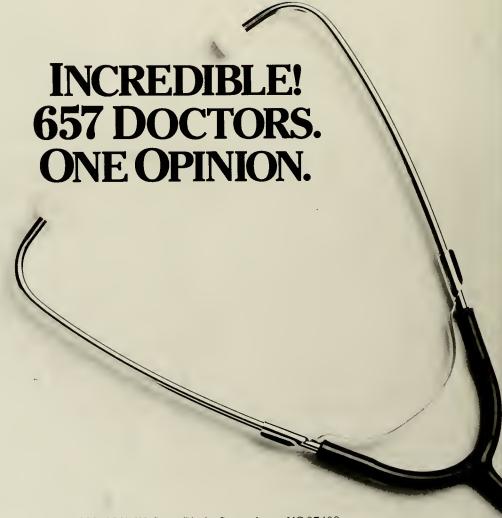
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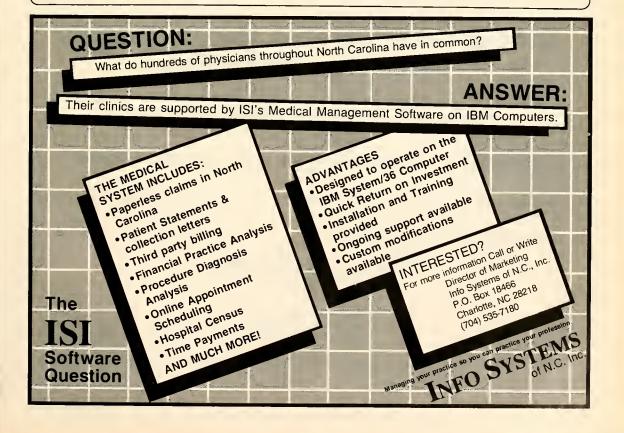
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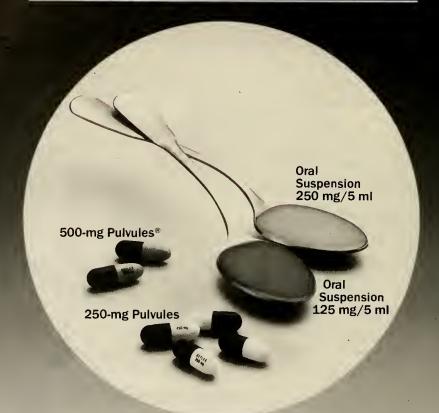
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## Tort Reform

George E. Moore

MY purpose, on behalf of the physicians of the state, is to recommend some solutions to the medical liability problem. We know, first of all, that there are no easy solutions. We know, and the citizens of North Carolina should know, that this is a terribly complex issue. No single profession or industry group is responsible for its problems. Let us not point an accusing finger. In my judgment, there is already far too much heat and smoke and too little light on the issue. We should avoid the acrimony that has characterized efforts like ours in other states. The real issue, amid all the smoke, is that the system for resolving medical liability claims eventually touches every citizen of the state. When it works well, it is a major social asset; when it works poorly, its failings eventually harm everyone. Given the present environment, we believe that it is a flawed system. The creation of the Medical Malpractice and Medical Liability Study Commission gives the citizens of the state an opportunity to study the system as an integrated whole and to improve its imperfections. We hope that our suggestions will lead to informed and dispassionate debate as the Commission considers the best possible means for dealing with the issue of medical liability in our state. Let me offer some recommendations.

#### Improved Policing and Self-Discipline of Physicians

It is not accidental that this is first among our suggestions. The vast majority of members of the North Carolina Medical Society do not want incompetent colleagues protected under a ''conspiracy of silence.'' The marginal practitioner is an unwelcome member of the profession. He is a very small minority of the profession but he gives an undeserved black eye to the overwhelming majority who are highly skilled men and women concerned first and foremost with the well-being of their patients.

It is the Medical Society's intention to ferret out those few bad apples. Our current President, Kenneth E. Cosgrove, M.D., has been responsible for a number of initiatives that will help us better identify and affect positively those members who overutilize the available health care resources, who overcharge, who practice substandard medicine, who are impaired, etc.

Let me emphasize, however, that the malpractice case involving the marginal practitioner is the exception. Most malpractice cases involve physicians who are fully qualified. Often it is the best ones who are accused of malpractice. But let it be said clearly: we recognize that

malpractice exists. We acknowledge that some patients are injured as a result of physician error. We believe that the patient should be compensated in a fair and timely manner. We need legislative action that will give physicians and appropriate agencies greater ability to prevent maloccurrences, and we need greater immunity from civil action when they participate in peer review and disciplinary activities. But we are hindered at every turn in this by restrictive and confusing laws that allow self-discipline on the one hand but create severe liability exposure on the other. In recent months, immunity and confidentiality were upheld in one state for physicians participating in a review of their colleagues, but in another state the reviewing physician was convicted of antitrust violations and ordered to pay more than \$1,000,000 to the plaintiff physician. Peer review is a long, difficult and uncomfortable process but one we are committed to doing.

We have presented a proposal to a major national foundation for a four-year grant that would give us generous financial support to develop studies and models that just might make North Carolina a leader for other states in achieving understandings and modifications of physician behavior through peer intervention. We have outlined another program that would be a joint effort with a state agency. We have a serious commitment to this goal of more effective self-policing of the medical profession.

We believe that the following five specific legislative actions would be extremely useful:

- Each company that provides health care insurance in
  the state shall (a) make information available to state
  licensing boards about awards for damages against the
  professionals under their jurisdiction, (b) establish programs for risk management for their insureds and (c)
  require each insured as a condition of maintaining insurance to participate in such programs at least once
  every three years.
- 2. Each state board shall enter into agreements with state or county professional societies to permit the societies to review information concerning practice patterns of health care professionals. Such agreements shall provide that the review occur expeditiously, that the society report its findings to the state agency, that it take such other action as it considers appropriate, and that the review and reporting preserve confidentiality of medical information and the review process. All such activity shall be immune from state civil or criminal liability, including antitrust. Patient information shall not be subject to discovery or subpoena, and review shall not be a breach of patient records' confidentiality.

From Box 27167, Raleigh 27611.

Remarks to the Medical Malpractice and Medical Liability Study Commission, March 13, 1986.

- Licensing boards shall have appropriate disciplinary prerogatives, investigatory power, and immunity for the entity and its members.
- 4. Hospital medical staff peer review and policing shall be encouraged by providing such activity with adequate immunities and protections and by establishing appropriate communications with the North Carolina Board of Medical Examiners.
- 5. We believe that punitive damages are intended as compensation for willful and malicious harm. If a physician's conduct is so outrageously malicious and harmful to a patient, the physician ought to be tried in criminal court on a felony charge rather than in a civil court as part of a malpractice proceeding. If convicted, the physician would be subject not only to the penalties prescribed by law but also to appropriate disciplinary action by the Board of Medical Examiners and professional associations, up to and including loss of license to practice medicine.

We cannot talk for long about solutions without talking about the tort system, that complex web of rules, institutions, and insurance mechanisms that has evolved for the purpose of deciding which injuries should be compensated, who should do the compensating and how much compensation is enough. The legal rules governing this system have their roots in a Common Law tradition that began in Britain in the ninth century and have evolved through case-by-case decisions in British and American courts for more than a thousand years. Over the centuries, the tort system has taken an irregular course because it always has to respond to changing social demands.

It is immensely difficult to determine which modifications to current law hold the greatest promise of equity to all involved. The issues are so complex that any change requires a balance of pluses and minuses. In weighing the many options, the North Carolina Medical Society has rejected all but a handful because their implications are so uncertain that they present more risk than promise. This is a serious business, and we believe that the recommended steps that follow will significantly improve the ability of the tort system to accomplish its purpose. We obviously have our own interests, but we offer these adjustments to keep the tort system as a dynamic and changing force that mirrors the needs of the times.

# Recommended Tort Reform #1: Mandatory Periodic Payments for Awards of Future Damages Exceeding \$100,000

Periodic payments of awards, known as "structured awards" or "structured settlements," are in general use in many states and foreign countries. Payments are guaranteed through the establishment of a trust fund or the purchase of an annuity. Structured settlements are reasonable in that awards are intended to provide for the support and treatment of the injured person in years to come, not to provide a huge one-time payment. Perhaps more important, a defendant deprived of the periodic payment mechanism may be required to liquidate all of his or her assets immediately and on highly unfavorable terms in order to pay a judgment that could be met with much

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greater ease and certainty if it were spread over the years to which it is supposed to apply.

Structured settlements could reduce insurance rates because the cash involved in the judgment would be left with the insurer to earn interest which would help to offset the effect of the judgment on the company's assets. The premium rates for an annuity or payment to a trust fund which guarantees support of the injured person total considerably less than one large settlement. The compounded value of money over time results in substantial savings for the insurer.

Predicting life expectancy is an error-prone activity. Making such predictions where the subject has suffered an injury serious enough to justify a large award for future losses is even more difficult. Sadly, it often results in large windfalls to beneficiaries whose financial dependence on and emotional linkage to the deceased have been slight or non-existent. Justice and the purposes of the compensation would be better served if specific provisions were made in the award that, in the event of the plaintiff's death, sums would be transferred to a surviving spouse, children, and other dependent heirs, if any, and the remainder would revert to the defendant.

The nationally known accounting firm of Milliman and Robertson has done an exhaustive actuarial analysis of this and three other tort changes we recommend. The initial savings estimated to be realized by the four tort reforms are for medical professional liability only. Under the statistical models described, initial premium savings of one billion dollars nationally are estimated. Obviously, the total savings would be astronomically larger if applied to the whole range of liability insurance and to additional reforms. For structured settlements as presented, the estimated savings are 6% of medical liability premiums. Total annual medical liability premiums in North Carolina are estimated at approximately \$35,000,000. Mandatory structured settlements would save an estimated \$2,100,000.

#### Recommended Tort Reform #2: Reduction of Awards Received by Compensation from Other Sources (Elimination of Collateral Source Rule)

The traditional collateral source rule in tort cases forbids evidence that the plaintiff has received compensation from other sources, such as insurance. Thus, a patient may receive compensation from more than one source for a single element of loss, such as medical expenses. Mandatory set off from payments of such collateral sources will prevent double compensation.

It is difficult to understand why a jury, as it awards damages, should not have before it all the relevant facts. We find it especially troubling that collateral source payments are not admissible even when the injured person did not contribute, by way of premium or otherwise, in obtaining collateral benefits. For example, if an injured person will be paid a monthly sum under a federal or state rehabilitation program for the cost of rehabilitation treatment, it seems unfair to allow an uninformed jury to order a physician to pay the patient a second time for the same treatment. The estimated initial savings are 8% of annual premiums, approximately \$2,800,000.

# Recommended Tort Reform #3: Modification of the Statute of Limitations (the Time Period within Which Civil Actions Must Be Commenced)

No claim may be commenced unless filed within three years from the date of the occurrence of the alleged act, except that a minor under the age of five years shall have until his eighth birthday in which to commence a claim.

The statute of limitations shortens the long tail of claims. The shortening of the limitation period applicable to minors will help ensure pertinent evidence when witnesses are available, allow insurers to better estimate awards and claims, and protect defendants against changes in legal doctrine and the risk of being judged on the basis of new knowledge. It protects the defendant from the inflation factor of verdicts increasing over time while the insurance coverage is frozen to the amount in place at the date of the alleged incident.

Consider the special plight of physicians who practice obstetrics in this state. Adjusting the statute of limitations for minors would be tremendously beneficial in arresting the alarming trends endured by these physicians over the last several years. An ever-growing fear of being sued, coupled with astronomical premium increases, is forcing many obstetricians and family physicians who do obstetrics out of practice. This has ominous consequences for the citizens of our state, especially those who live in non-urban areas. Access to care will be a problem. There will be shortages of medical care. And there will be a worsening of our present infant mortality rate problem.

# Recommended Tort Reform #4: Limitation of Awards of Non-Economic Damages

The amount of any award of damages for non-economic losses should be limited to a certain amount, including losses for pain, suffering, mental anguish, inconvenience, etc.

There are inherent difficulties in placing monetary value on non-economic damages. Since the setting of such damages is so subjective, widely differing awards in similar situations frequently occur. Limits will provide more equity between awards.

Juries are presented with allegations that pain and suffering can be measured out and priced on a dollar basis. Translating emotional damage into dollar equivalents always has been and always will be an arbitrary process. We believe it would be useful, however, to develop standards of comparison from a large body of cases and to form appropriate compensation levels for each injury category. Perhaps a State Commission could be created with a mandate to study and develop sample standards of reasonable awards for non-economic damages which would be used as general but not absolute guidelines with which juries would be acquainted before rendering judgments.

The actuarial estimate of initial savings is 12% of professional liability premiums, approximately \$4,200,000.

# Recommended Tort Reform #5: Limitation of Award for Mandatory Procedures (DPT vaccine)

Damages for injury resulting from a medical procedure mandated by law, such as giving DPT injections, shall not exceed \$250,000, unless additional amounts are ordered by the court. Health care providers should be protected from excessive risks of loss when performing medical procedures mandated by law. The state may choose to develop a compensation fund, discussed below, for injuries resulting from these procedures. The North Carolina Medical Society will work closely with other interested groups in the refinement of this proposal.

#### Recommended Tort Reform #6: Limitation on Awards and Development of a Patient Compensation Fund

Damages for liability by a health care provider may not exceed \$500,000; further, a health care provider is not liable for an amount in excess of \$100,000 per occurrence, and any amount over that shall be paid from the Patient Compensation Fund (PCF) which shall be created by the state, funded by an annual surcharge on health care providers in the state, determined upon actuarial principles and collected on the same basis as premiums by professional liability insurers.

This limitation of awards would reduce costs to benefit all consumers and would guarantee the availability and affordability of health care. With a limitation on payments, a viable patient compensation fund can be established to help ensure solvent sources of insurance for plaintiffs and make it easier for insurers to estimate liability.

The State of Indiana enacted such legislation several years ago. All reports indicate a highly positive experience, and the system has since withstood a challenge to its constitutionality. Even though health care providers fund the Patient Compensation Fund through a surcharge on liability premiums, their total outlays should diminish because the Fund essentially performs a reinsurance function. Reinsurance these days is an expensive and increasingly scarce commodity. There are no domestic companies willing to write such coverage in North Carolina, and Medical Mutual Insurance Company has to negotiate its reinsurance treaties with Lloyd's of London. Present terms require a deductible of the first \$192,500 of an award before the reinsurance coverage begins, up from \$100,000 just a few months ago. Annual increases in the deductible are now part of the treaty agreement.

It is essential that there be a maximum award if a Patient Compensation Fund is created because a few extraordinary awards could deplete its resources. We offer this recommendation in full awareness of its potential impact on the severely injured party. With a structured settlement program of the kind discussed earlier, the \$500,000 "cap" recommended could purchase an annuity sufficient to compensate the injured person fully for economic losses for the balance of his or her life. For instance, a three-year old boy would receive a \$51,586 cash payment immediately and monthly payments beginning at \$1,330 that increase annually by 6% to \$125,230.00 at the 75th year (his actuarial life expectancy). Total payments over that period, for a \$500,000 award, would be \$25,580,540. (These are exact numbers taken from an insurance company's bid on January 28, 1986.) Obviously, each settlement should be structured for the specific needs of the injured person. With appropriate safeguards, all parties can benefit.

# Recommended Tort Reform #7: Refinement of Qualifications for Expert Witnesses

In addition to current requirements, an expert, to qualify to testify, must be qualified as an expert within the specialty of the defendant and be currently in active practice of that specialty.

The battle of the experts is to many people one of the most depressing aspects of the tort system. It often appears that there is no position on any side of an issue on which it is impossible to enlist the support of an expert witness. There is emerging a breed of "professional experts" whose livelihood depends on traveling from court to court to serve the interests of the party paying the bill.

Because "experts" are distinguished in the law primarily because they can testify to opinion as well as to fact, an expert witness must be truly that. The suggested safeguards will protect the system by ensuring that witnesses testifying as experts are intimately familiar with the applicable standard of care in this age of increased specialization of health care disciplines. We are not recommending that experts be restricted along geographic lines.

# Recommended Tort Reform #8: Limitation of Attorneys' Fees

When a plaintiff receives a settlement or an award for damages, the payment to the individual's attorney shall not exceed a sliding scale percentage amount that reduces as the amount of the total settlement or award increases, unless the court orders additional payment.

The limitations on attorneys' fees will ensure that reasonable amounts go to the injured plaintiff without denying the attorney fair compensation, will encourage earlier settlements by removing incentives to pursue large jury verdicts and therefore larger fees and will reduce incentives to take cases that have doubtful merit but hold hope for a huge recovery.

The United States is one of a handful of nations in the world that permits plaintiffs' attorneys to set their fees as percentages of either court awards or settlements. Many responsible authorities, including the entire British Bar and those of most other countries, argue for abolition of the contingency fee and its replacement by the standard feefor-service arrangement typical of other areas of law and of professional services in general. We have carefully considered the arguments advanced by people who hold this view, but we remain unconvinced. In our view the contingency fee performs functions which would not be as well performed by other procedures. Principally, it is a powerful discouragement to frivolous or lightly considered suits, and it assures access for the poor to legal services which would not be provided in any other way in the absence of a Legal Aid mechanism many times the size of the one now in existence. Therefore, we do not recommend that the practice of charging contingency fees be made illegal.

However, legitimate questions about proper limits on contingency fees have arisen. Too little goes to the injured party from awards.

A statute should be enacted placing a quantitative limitation on contingency fees. Contingency fees should be calculated after the deduction of plaintiff's non-recoverable costs. The schedule, for example, might limit fees to not more than 33½% of the first \$150,000 in damages, 25% of the next \$150,000, and 10% of the balance of any damages awarded. If the case is settled prior to decision, the corresponding percentages might be 25%, 18%, and 6%. The court awarding a judgment should be authorized to increase the permissible fee upon a petition which justifies additional compensation. Initial savings are estimated to be 9% of annual premiums, approximately \$3,150,000.

## Recommended Tort Reform #9: Countersuits to Frivolous Suits

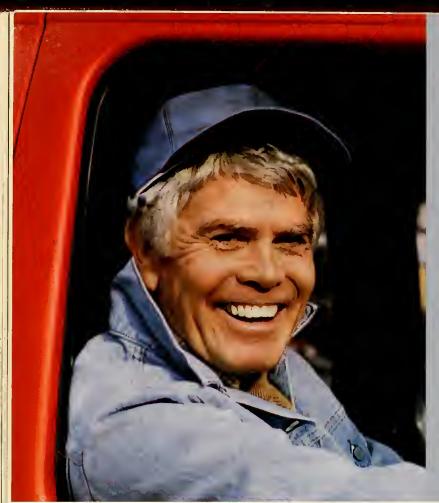
The defendant shall have a cause of action against the plaintiff and/or the plaintiff's attorney upon a determination by the court that the suit is frivolous.

Non-meritorious suits are an expensive drain on resources and should be discouraged. Current North Carolina countersuit laws are too weak to be effective deterrents.

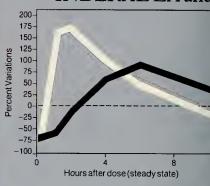
There is no direct counterpart in civil law to the "probable cause hearing" employed in criminal proceedings, in which the prosecution is required to demonstrate that there is a solid basis for the action. Thus, even a tort suit with no semblance of merit can exact huge financial and emotional costs on the defendant for years before a determination is made. One liability carrier estimates that just the filing of a claim generates a cost of approximately \$20,000 in legal fees alone. More than 80% of malpractice claims in North Carolina are closed with no payment, but they take their toll on the defendants in the process. In today's climate there has grown up the notion that a dissatisfied patient is a mistreated one, entitled to his day in court no matter how frivolous his claim. It is a sad fact of life that an adverse outcome can result from the very best care. But the steady advance of medical science, which routinely produces results that would have been considered miracles just a few years ago, has raised patients' expectations to unrealistic levels. Anything less than perfection too often triggers a rush to litigation. The time and facilities of the justice system could be freed for the serious cases if a more effective means of bringing charges against an irresponsible party are provided as a deterrent.

We think these suggested reforms are realistic and fair. We think they will stand the test of constitutionality. And we know they will reduce health care costs considerably in this state. Except for one or two that address medical situations specifically, these changes are applicable generally to the tort system and do not represent special interests.





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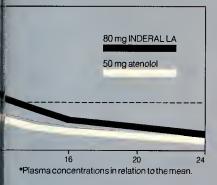
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Propranolol hydrochloride (INDERAL® LA): CAROIAC FAILURE Sympathetic stimu-Propranolol hydrochloride (INDERAL® LA): CAROIAC FAILURE Sympathetic stimu-lation may be a vital component supporting circulatory function in patients with congastive heart failure, and its inhibition by beta blockade may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, it necessary, they can be used with close follow-up in patients with a history of failure who are well compensated, and are receiving digitals and durefics. Beta-adrenergic blocking agents do not abolish the inotropic action of digitals on heart muscle.

digitals on heart muscle
IN PATIENTS WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases, lead to cardiac failure Therefore, at the first sign or symptom of heart failure, the patient sign of symptom of the symptom

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina IN PAILENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction following abrupid discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned the dosage should be gradually reduced and the patient carefully monitored in addition, when propranolol is prescribed for angina pectoris, the patient should be cautioned against interruption or cessation of therapy without the physicians advice if progranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol therapy and take other measures appropriate for the management of unstable angina pectors. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS Bela blockade may mask certain clinical signs of hyperthyroidism Theretore, abrupt withdrawal of propranolol may be followed by an exacetbation of symptoms of 
hyperthyroidism, including thyroid storm Propranolol does not distort thyroid function lests 
IN PATIENTS WITH WOLFF PARKINSON-WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a 
demand pacemaker in one case this resulted after an intial dose of 5 mg propranolol 
MAJOR SURGERY The necessity or desirability of withdrawal of bela-blocking therapy prior to 
major surgery is confroversal it should be noted, however, that the impared ability of the heart to 
respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical 
procedures.

procedures

Nonallergic Bronchospasm (eg, chronic bronchitis, emphyseme)—PATIENTS

WTH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS

INDERAL should be administered with caution, since it may block bronchodiation produced by
endogenous and exogenous catecholamine stimulation of beta receptors

DIABETES AND HYPOGLYCEMIA Beta addrenergic blockade may prevent the appearance of
certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in labelie insulin-dependent diabetes. In these patients, it may be more difficult to adjust
the dosage of insulin Hypoglycemic attacks may be accompanied by a precipitous elevation of
blood pressure.

Hydrochlorothiazide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thiazides may precipitate azotemia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate horotherage.

hepatic coma

spatic coma
Thiazides may add to or potentiale the action of other antihypertensive drugs. Potentiation cours with ganglionic or peripheral adrenergic-blocking drugs. Sensitivity reactions may occur in patients with a history of allergy of bronchial asthma. The possibility of exacerbation or activation of systemic lupus erythematosus has been

#### PRECAUTIONS

PRECAUTIONS

Propranolol hydrochloride (INDERAL® LA): GENERAL Propranolol should be used with cauthon in patients with impaired hepatic or renal function, Propranolol is not indicated for the treatment of hypertensive emergencies.

Beta adrenoreceptor blockade can cause reduction of intraocular pressure Patients should be told that propranolol may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure.

CLINICAL LABORATIONY ERST. Elevated blood urea levels in patients with severe heard disease elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase.

DRUG INTERACTIONS Patients receiving catecholarimie-depleting drugs, such as reserpine should be closely observed if propranolol is administered. The added catecholarimie-blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hyporlession, marked bradycardia, verligo, sympopal attacks, or orthostate hypotension between the propranolol states of the propranolol states and most employed specifically related tumorgenic potential in 18 month studies, in soft rate and most employed prelated tumorgenic clients at any of the dosage levels reproductive studies in animals do not show any impariment of fertility that was attributable to the drug.

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drug 
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NUASING MOTHERS. Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother. PEDIATRIC USE Safety and effectiveness in children have not been established. Hydrochlorothiazide: GENERAL. Periodic determination of serum electrolytes to detect possible electrolyte imbalance ashould be performed at appropriate intersity. All patients receiving thiazide therapy should be observed for clinical signs of fluid or electrolyte imbalance, namely. Hybonarremia, hypochloremic alkadosis, and hypokalemia. Serum and urne electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitals may also influence serum electrolytes. Warning signs irrespective of cause are Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pains or cramps, muscular fatique, thypotension, oliguria, tachycardia, and gastronitestinal disturbances such as nausee and vomiting. Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present or

gastrointestinal disturbances such as nausea and vomiting. 
Hypokalemia may develop, especially with brisk diuresis, when severe cirrhosis is present, or during concomitant use of corticosteroids or ACTH interference with adequate oral electrolyte indake will also contribute to hypokalemia. Hypokalemia and sensitize or exaggerate the response of the heart to the toxic effect of digitalis (eg. increased ventricular irritabitity). Hypokalemia may be avoided or freated by use of pofassium supplements, such as foods with a high pofassium content. Any chloride deficial segenerally mild and usually does not require specific treatment, except under extraordinary circumstances (as in liver or renal disease). Diuttional thyponatremia may occur in edematous patients in hot weather, appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is like-threatening. In actual salt depletion, appropriate replacement is the therapy of choice.

Hyperuncemia may occur or frank gout may be precipitated in certain patients receiving thiazalde therapy.

Hypertricemia may occur on the may be increased, decreased, or unchanged. Diabetes mailifus which has been latent may become manifest during this acide administration. If progressive renal impairment becomes evident, consider withholding or discontinuing duretic therapy.

It progressive renal impairment becomes evident, consider withholding or discontinuing diuretic therapy. Thiazides may decrease serum PBI levels without signs of thyroid disturbance. Calcium excretion is decreased by thiazides. Pathologic changes in the parethyroid gland with hypercalcema and hypophosphatema have been observed in a few patients on prolonged thiazide therapy. The common complications of hyperparathyroidsm, such as renal lithiasis, bone resorption, and peptic ulceration, have not been seen. Thiazides should be discontinued before carrying out tests for parathyroid function. DRUG INTERACTIONS Thazide drugs may increase the responsiveness to tubiocuranne. The antihypertensive effects of thiazides may be enhanced in the postsympathectomy patient. Thiazides may decrease afterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use. PREGNANCY Pregnancy Category C Thiazides cross the placental barrier and appear in cord blood. The use of thiazides in pregnancy requires that the anticipated benefit be weighed against possible hazards to the fetts. These hazards include fetal or neonatal jaundice, thrombocylopenia, and possibly other adverse reactions which have occurred in the adult. NURSING MOTHERS Thrazides appear in human milk. If use of the drug is deemed essential, the patients should stop nursing.

the patient should stop nursing PEDIATRIC USE Safety and effectiveness in children have not been established

#### ADVERSE REACTIONS

ADVERSE REACTIONS
Propranolol hydrochloride (INDERAL® LA): Most adverse effects have been mild and
transient and have rately required the withdrawal of therapy.
Cardiovascular Bradycardia, congestive heart failure, intensification of AV block, hypotension,
paresthesia of hands, thrombocytopenic purpura, arterial insufficiency, usually of the Raynaud

paresthesia of narius, truminous productives, mental depression manifested by insomna, Central Nervous System Lightheadedness, mental depression progressing to catalonia, visual disturbances, hallucinations, an acute reversible syndrome characterized by disorientation for time and place, short-term memory loss, emotional lability, slightly clouded sensorium, and decreased performance on neuropsychometrics Gastrointestinal. Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, consti-

decreased performance on neuropsychometrics. Gastronitestrial Nausea, worming, enjogastric diskress, abdominal cramping, diarrhea, consti-pation; mesenteric arterial thrombosis, ischemic colitis. Allergic Pharynghis and agranulocytosis, erythematicus rash, lever combined with aching and sore throat, laryngospasm and respiratory distress. Respiratory Bronichospasm Hematologic Agranulocytosis, nonthrombocytopenic purpura, thrombocytopenic purpura Auto-Immune In extremely rare instances, systemic lupus erythematosus has been reported Miscellaneous Alopecia, LE-like reactions, psorrasiform rashes, dry eyes, male impotence, and Peyronics disease have been reported rarely. Oculomucocutaneous reactions involving the skin.

serous membranes, and conjunctivae reported for a beta blocker (practolol) have not been ssociated with propranolol

associated with proprianolot 
Nydrochlorothiazide: 
Gastrointestinal Anorexia, gastric irritation, nausea, vomiting, cramping, diarrhea, constipation, 
jaundice (intrahepatic cholestatic jaundice), pancrealitis, sialadenitis 
Central Nervous System Orzeness, vertigo, paresthesias, headache, ranihopsia 
Hemalologic, Leukopena, agranulocytosis, thrombocytopenia, aplastic anemia. 
Cardiovascular Orthostatic hypotension (may be aggravated by afcohol, barbiturates, or 
narcolisis).

narcotics). Hypersensitivity Purpura, photosensitivity; rash, urticaria, necrotizing angitis (vasculitis, cutaneous vasculitis; fever, respiratory distress, including pneumonitis; anaphylactic reactions Other Hyperglycemia, glycosuria, hyperuricemia, muscle spasm, weakness, restlessness, transient blurred vision. Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or therapp withdrawn. "The appearance of these capsules is a registered trademark of Ayerst Laboratories

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# The Politics of Liability Reform

H. David Bruton, M.D.

YOUR editor asked me to describe the political strategy of our liability reform campaign. I do not recall ever having seen in a public press, in written form, a description of a political strategy until after the campaign. The student in me found it hard to say no to a Professor of Medicine. The politician in me knows that with the aid of the retrospectroscope a political campaign can be made to look a lot smarter than a prospective description is likely to appear.

It was clear in the summer of '84 that there did not exist outside the medical community a sense of crisis about the medical liability problem. Certainly at that time the North Carolina General Assembly was not ahead of the citizens on this issue. We convened a task force on medical liability to test and advertise the notion that a legislative study commission was the correct vehicle to focus attention on the issue and to educate the public and their legislators.

In the '85 session of the legislature a Medical Malpractice and Medical Liability Study Commission was established with sufficient funding to do a comprehensive study of the issue. Some very interesting eleventh hour politicking was required to create the commission.

Early on we established several principles to guide our political actions. An over-riding concept was that the medical malpractice problem was not a doctor/lawyer problem, but a problem of public policy for citizens at large. We were not likely to have our citizens demand the necessary legislative solutions to a special-interest issue. That contest could be seen too easily as greed vs. greed. Even though it is not entirely true, we constantly advanced the argument that malpractice costs were simply, directly or indirectly, passed on to the consumer. We have tried to characterize Medical Mutual Insurance Company, our non-profit captive, as merely a conduit with appropriate reserves.

A Liability Reform Steering Committee was formed within the Medical Society with comprehensive specialty and geographic representation. A strong effort of that committee is to involve business and industry leadership through the use of business/health coalitions, local and state governmental leadership, allied health professional organizations and our own local medical society components. The idea is that we will provide all of the staff help possible, as well as educational materials and coordination, all the while trying to force out front spokespersons and

activities that seem to come from sources other than the Medical Society. There is no limit to what we can accomplish if we don't waste any energy on who gets the credit. A lot of our most effective activity is behind the scenes.

Another parallel activity that is extremely important in our efforts is the Liability Insurance Availability Study Committee. The cost of liability insurance has reached a level at which coverage is unavailable to large numbers of businesses and individuals. This committee has provided important counterpoint to the work of the Medical Liability Study Commission. We are providing significant support to the chairman of that committee. The chairman sees an opportunity to address a major public policy problem through the work of his committee.

Our immediate efforts are directed toward tort reform. (You are referred to George Moore's article in this issue of the *Journal* for a review of the specific reforms we propose.) We constantly point out that the reforms we seek are generic in nature, not special-interest legislation. All would apply to the resolution of general and product liability problems the same as they would to professional liability problems. The only special-interest legislation we seek is in the area of medical discipline.

Another early decision was that our campaign would not be shrill or loud. We do not plan any marches on Raleigh, withdrawal of services, or big money political activities. Several state medical societies have spent millions on losing campaigns. We have chosen to make our case with evidence and reason. That does not mean that we do not plan to be tough. We simply are going to be physicians. Interestingly enough, it is this aspect of the strategy that has collected the most criticism from our membership. Some confuse gentleness and good humor with softness and irresolution.

It should be pointed out that if we accomplish all the tort reforms we seek it will not solve the malpractice problem. Improved professional discipline, contracting arrangments that preclude access to the courts, publicly insured no-fault compensation plans for bad outcomes, claims settled by scientifically trained panels instead of lay juries are all concepts that must be studied as replacements for the inefficient, unfair and unjust system now in place.

If we are to accomplish our goals, both short and long term, each one of us must do our part by becoming an informed advocate for our patients' right to be free from the destructive effects of our present liability resolution system. Please join the effort to educate the public and their representatives to the General Assembly.

# 

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# LIABILITY PROPHYLAXIS

John A. Henderson, M.D.

IT isn't necessary to tell a physician about the liability crisis. Unless he has been out of the country, in hibernation, or works for an organization that prints its own money, the results of recent settlements are well known. Because of the indignant outcry of municipalities, businesses, insurance companies and for that matter anyone who is producing a product or delivering a service, there is a good possibility that some changes in the tort system will be forthcoming. Even with those changes, however, we cannot expect more than a mere slowing of the increase in the cost of liability insurance. Until juries and judges begin to understand cause and effect, contributory negligence and risk taking, we will see little improvement. If the courts persist in using the tort system to redistribute wealth, if they insist on perfect results and absolute liability, if they continue to adhere to the "deep pocket theory," we can expect little relief. A system that will result in a fair and just settlement for all concerned will require more than tort reform, though that is a most important first step.

If the above premise is correct, we physicians must cope with medical liability for years to come. With that in mind we must continually remind ourselves to practice prevention. Certainly the old admonition, "an ounce of prevention is worth a pound of cure," is doubly germane in this issue. Once we realize that prevention of liability suits is essential today and for the years to come, we must continually review our practices and our relationships with our patients. Much of this knowledge is common sense but one of the surprises of life has been how uncommon common sense can be.

The sine qua non of prevention is good doctor-patient relationships. While good doctor-patient relations will not always prevent a suit, certainly a poor relationship will cause one. All physicians as well as their office personnel must constantly remind themselves that PEOPLE DON'T SUE THEIR FRIENDS. With that in mind let me give you some pointers on HOW TO LOSE FRIENDS AND ALIENATE PATIENTS.

Play God. Be all knowing, all righteous and all powerful. Be aloof and above it all. Talk down to patients. What do they know? Charge high fees and push for last dollar collections. Especially if you have had a bad result or complication, go for collection of the full fee. It's not your fault if a patient turned sour and gets angry.

Make patients wait for you. Your time is more important than theirs. If there is one thing patients don't like, it's

sitting in the waiting room or examining room not knowing when they will be seen and not given an explanation. Be sure to look busy and hurried. Don't be available. Don't return your phone calls. Don't allow patients the time and opportunity to ask their simple stupid questions. If you can slip in a personal insult, so much the better. An insult to another member of the family about the patient works wonders, too.

Train your office help to take care of your needs, not the patient's. Hire an insensitive battle-ax to be your receptionist and support her when she tells a patient off. After all, the office staff are your help, not the patient's.

Certainly with the above suggestions you should have no difficulty making your patient and the patient's family angry. That is the first ingredient of a liability suit. The next requirement for a successful suit is a complication or bad result. If you have no complications, no bad results and all of your patients get well on schedule, you need read no further. For those of you who do have an occasional complication, perhaps you'd better continue.

As a result of medical practice surveys performed by our own Medical Mutual Insurance Company, we now know the most common causes for losing liability suits. If one has an unhappy patient with a bad result one must consider the following causes:

- 1. Failure to note drug allergies and act accordingly.
- 2. Failure to initial or sign diagnostic studies or otherwise acknowledge that you have seen them and responded properly. Unfortunately in our present tort system you are guilty until proven innocent. The present attitude of the Court appears to be if you haven't written it down you haven't done it.
- 3. Failure to obtain informed consent. Fortunately in North Carolina the law further stipulates that a reasonable person would not have had the procedure performed after informed consent. This is a great advantage to North Carolina physicians.
- 4. Failure to have a staff member certified in cardiopulmonary resuscitation. If a reaction occurs in your office or surgery and no one is trained in CPR, throw in the towel.
- 5. Failure to have an adequate failsafe system on pathology, lab, x-ray reports etc. Make sure all your studies get back to you and are properly noted and responded to. It will be very difficult to explain to a jury why an abnormal report was not followed up promptly. They don't care if the mail didn't get delivered or there was a breakdown in communications.
  - 6. Delay in diagnosis. It is impossible to convince peo-

ple that a delay in diagnosing a breast lump, rectal bleeding, etc. is not the direct cause of a bad result. This is especially true after convincing the public that they should promptly see their doctor when one of these symptoms is present.

7. Finally, if you really want to help the plaintiff's lawyer, alter the medical records and get caught at it. You probably won't have to show up in court as your insurance company will allow the plaintiff's lawyer to fill in the amount.

Whether or not a physician gets sued usually depends on how well patients and their families are handled when a complication, surprise or untoward result occurs. As one surgeon remarked, "If all goes well I don't worry, but if I get a complication or bad result I make that patient and their family a member of my family. I love them and support them."

In summary, perhaps all that is written can be summarized in the four As:

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# Irritable Bowel Syndrome

Michael E. McLeod, M.D.

THE irritable bowel syndrome, although usually referring to colon disorders, can be viewed as including a spectrum of esophageal, gastric and colonic-derived symptoms. In this model a muscular digestive tube either has abnormal motility or the sensations of normal motility are misperceived resulting in the symptoms. More sophistication in the use of manometry, increasing knowledge of enteric nervous system and understanding of the link between the central nervous system and the intestinal tract with peptide hormones promise increasing understanding of normal and abnormal intestinal function in the future. Despite gaps in our current knowledge, irritable bowel syndrome is an extremely important disorder.

Epidemiological surveys suggest that up to 32% of the general population experience symptoms of the irritable bowel syndrome even though a much smaller percentage actually seek medical attention. Because the multiple symptoms including nausea, vomiting, diarrhea, constipation and abdominal pain occur in the setting of normal laboratory and x-ray studies, there is a great deal of misunderstanding by both patient and physician as to the nature of the problem. Patients find it hard to understand how the bloating, tender palpable masses (loops of distended bowel) and diarrhea can occur and no reason for these changes be discovered by extensive testing. Physicians, in addition, frequently tell patients to learn to live with it without attempting to explain the mechanism of the symptoms or to educate the patient as to how to alter the pattern of symptoms. The combination of symptoms, in particular the abdominal pain, reported by the patients frequently leads to unnecessary medical and surgical therapy. In many instances surgery is carried out for gallstones, hiatus hernia, diverticular disease, hysterectomy, removal of adhesions when, in fact, the symptoms reported by the patient are unrelated to the findings on x-ray or at surgery.

In understanding the irritable bowel syndrome it is important to know that changes in function are traditionally detected by patients before the doctors identify the anatomical differences responsible for the altered functions. When the doctor says that the symptoms cannot be explained by the tests he is merely stating that the anatomical arrangement in the bowel, the brain and the endocrine glands responsible for the symptoms has not yet been worked out by the scientists and that he has found no

destructive processes that will shorten the life of the patient.

The era of electron microscopy and molecular biology has allowed us to identify anatomical changes that were not identifiable in the area of gross and light microscopic pathology. For example, lactase deficiency and acute intermittent porphyria are molecular diseases whose anatomical basis has only recently been identified. We use the term anatomical to define the state of structure at any level — gross, tissue, cellular, molecular. In exploring patients' symptoms we must ask at what level are we to look for their disease, i.e., gross or microscopic anatomy, molecular abnormalities, abnormal motility or other undefined level. In addition, the duration of the abnormality and method of measurement are important. Ulcers last weeks, erosions may last days and gastritis induced by alcohol may last hours. Spasm in the esophagus may be present for seconds to minutes. Hence, depending on whether we use x-ray, endoscopic exam, or motility measurements may determine whether or not we define an abnormality. If we do define an abnormality, we must attempt to see if it correlates with the patient's symptoms.

#### Disease vs. Illness

Disease is a biological event with anatomical, physiological and biochemical changes in the person. These may or may not cause an illness, i.e., a change in the patient in terms of symptoms or performance level. Asymptomatic coronary disease, silent peptic ulcer, G6-PD deficiency and silent gallstones represent molecular and anatomical diseases that can be present without the patient experiencing symptoms. Illness, on the other hand, is the experience of the patient in terms of 1) pain or discomfort; 2) alterations in performance levels such as weakness, fatigability, anorexia and 3) specific abnormality in body functions such as breathing, swallowing, defecation, etc. Again, it must be emphasized that the patient's illness may not correlate with a disease that we have discovered by our x-ray, endoscopic, laboratory or molecular examinations. The patient who is bloating and belching and complaining of upper abdominal pressure after each meal will not be helped by cholecystectomy except through its potential placebo effect.

The concept of psychological stress needs to be integrated into this model. Psychological stress can be defined as any process within the person or the environment that creates a demand, the resolution of which produces changes in the nervous system. Usually this involves loss or threat of loss, injury or threat of injury or frustration of an inner drive or need. It is important to emphasize that stress

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This article will be published later in 1986 as a chapter in the book, *The Complicated Medical Patient*, edited by Harry A. Gallis, M.D., and published by Human Sciences Press, Inc.

occurs in all individuals. Some stress is important in terms of normal growth and development. However, if stress accumulates and exceeds a certain threshold, certain physiological changes may occur in many organ systems, ranging from elevations in blood pressure to bronchospasm to changes in intestinal motility. The pattern of organ response may in large part be genetically determined. Many patients will report only the somatic symptoms and have no associated emotional component while other patients will experience the feelings of rage, fear or sadness along with the physiological event described above. There are some universal stressors such as major losses including death of a spouse or loved one, loss of a job, or loss of an organ such as breast or colon. Major surgery or lifethreatening accidents also represent universal stresses. However, there are certain stresses that are conditioned or learned in response to each patient's unique past history. A roller coaster ride may be exciting to some individuals but represent a major threat to others. Some personalities are stressed by self-imposed time pressures which are internally generated. There are some data suggesting that despite similar or different stressful stimuli the responsive organ system may be unique to the individual, perhaps genetically determined as in certain familial peptic ulcer syndromes or in patients with hyperactive airways seen in the asthmatic population. Additionally, there are situations in which there is a reward maintenance system with increasing family attention, avoidance of responsibilities, i.e., the "sick role," leading to secondary gain in the situation and perpetuation of the symptom complex.

Functional bowel syndrome is a heterogeneous group of disorders with symptoms originating from three portions of the gastrointestinal tract: esophageal with the patient presenting with intermittent chest pain and dysphagia; gastric in which the patient presents with nausea, early satiety, bloating and pain; colonic in which the patient's complaints relate to pain, bloating and change in bowel pattern. The general conceptual model frequently used to explain these disorders is that of a hollow muscular tube capable of regular, rhythmic, sequential and propulsive contractions; in certain locations and under certain conditions it may develop simultaneous contraction waves with changes in intensity, amplitude and duration of contraction producing retrograde flow and distention and, at times, partial obstruction. As a result, normal function is interrupted and the symptoms result.

#### **Esophageal Motility Disorders**

Esophageal motility disorders are more easily defined because of easier access and less complexity than gastric and colon disorders. There are primary muscle disorders such as achalasia and diffüse esophageal spasm with well-defined manometric criteria. There are also secondary muscular disorders like the hyperdynamic or "nutcracker" esophagus in which the abnormal motility occurs in several situations and appears to be secondary to other factors. In this group, the abnormal motility may be correlated with signs and symptoms of increasing emotional and psychological stress and many of these patients fit specific psychiatric diagnoses as defined by *Diagnostic and Statistical Manual of Mental Disorders*, Third Edition, published by

the American Psychiatric Association in 1980. In addition, mucosal and inflammatory changes such as reflux esophagitis may contribute to this abnormal motility pattern. The pain is typically described as squeezing, pressing and substernal in location frequently radiating to the back and neck. These patients may experience difficulty with swallowing including solids and liquids; a food bolus will frequently stop abruptly followed in several minutes by relief. The pain and dysphagia may occur separately or simultaneously. In this group of patients endoscopic examination is important to exclude the inflammatory changes, and motility studies are needed to determine the presence or absence of primary muscle disorders, i.e., achalasia and diffuse esophageal spasm. Since stress and associated psychological factors are often felt to be important, other changes in performance levels should be looked for including changes in energy level, early morning fatigue, altered sleep pattern, recurrent headaches, altered moods. Stable weight, hemoglobin, normal albumin and Westergren sedimentation rate also help support this diagnosis.

Esophageal motility disorders may produce substernal pressure and pain mimicking cardiac disease. Wells and Lustman reported 50 patients with negative coronary angiograms and atypical chest pain. Esophageal motility studies demonstrated that 25 of 50 had abnormal studies compatible with "nutcracker" or hyperdynamic esophagus. The 25 patients underwent psychological testing using stringent criteria outlined in DSM-III and 85% had a positive diagnosis including 13 with depression, five with somatization disorder, nine with generalized anxiety and seven with phobia. A control population had only 31% positive with DSM-III diagnosis. This study showed an increased association of atypical chest pain, negative angiograms and abnormal esophageal motility with an increased prevalence of psychiatric illness. The direct relationship of the pain to the motility pattern was not established in this study. In other studies, however, similar patients infused with Tensilon or Ergonovine have had their chest pain reproduced with simultaneous esophageal spasm noted on manometry.

#### Gastric Disorders

Gastric disorders include patients with 1) nausea, vomiting, early satiety in the setting of normal endoscopy; 2) aerophagia with bloating and abdominal distention frequently relieved by belching; 3) pain diffusely located, migrating to different quadrants of the abdomen vaguely described with multiple adjectives such as burning, aching, pressure, stabbing, etc. The symptoms vary in relationship to time of day and meals and tend to occur several days per week rarely going more than a week without symptoms. Symptoms are rarely nocturnal except in patients with depression where there may be early morning awakening between 3:00 and 5:00 a.m. In contrast, peptic ulcer disease tends to wake patients between 12:00 and 2:00 a.m., generally manifest daily pain and has a clear relation to meals with food either relieving or aggravating the pain. When these multiple gastric symptoms have been present intermittently for years with previous negative x-rays and endoscopy the diagnosis is not difficult. However, the onset of new symptoms of this type in a patient over 50 years of age in the absence of previous psychophysiologic disorders should prompt careful examination to exclude other diseases such as gastric ulcer and gastric malignancy.

Gastric motility measurements are still at a level of research interest and do not provide clinical help in managing these types of patients.

#### Colonic Disorders

The third and final group is the irritable colon syndrome or spastic colon, the most common of the three groups. Estimates suggest that up to 50% of consults to gastroenterologists are referred for this disorder. Unfortunately, there is no motility pattern that has been documented to be specific for this disorder. However, clinical criteria have been proposed by Manning et al and include the following:

1) Abdominal pain present in any or all four quadrants including lower chest and subscapular region. The lower abdominal area is the most common site with pain lasting from five to 30 minutes. The pain tends to be migratory and frequently is associated with abdominal distention and bloating and at times with palpable loops of bowel. The pain is often relieved by bowel movement or passage of flatus and frequently occurs with loose bowel movements, obstipation or frequent defecation with normal bowel consistency. The various pain types including the subscapular and lower chest pains have been reproduced in over 50% of one group of patients using colonoscopy and distensible balloon.

2) Altered bowel pattern is an almost universal complaint. Constipation with tapered bowel movements which fluctuate from normal caliber to narrow stool caliber indicating a variable degree of obstruction rather than the fixed obstruction of carcinoma is a frequent complaint. The pattern of alternating diarrhea and constipation is also common.

3) Abdominal bloating and distention are frequent symptoms. These often become worse as the day progresses and may or may not be relieved with passage of gas. Actual measurements of methane, hydrogen and nitrogen indicate that the majority of patients with functional colon syndrome do not pass excessive gas, but appear to handle it differently in terms of their motility pattern. Levitt has shown that by perfusion of Argon gas into the bowel of patients with irritable bowel syndrome they report many more symptoms than the control population with the same volume of infused gas.

4) Increased passage of mucus is often noted.

5) The sensation of incomplete rectal emptying is also frequently reported. Proctalgia fugax or intense pain within the rectum lasting minutes and occurring spontaneously is much less frequent.

The more of these symptoms reported to the exclusion of factors listed below will increase the sensitivity and specificity of the diagnosis of functional colon syndrome. The important exclusions include 1) significant weight loss; 2) blood loss except that identified as from the anal canal; 3) lactose intolerance; 4) abnormal hemoglobin, albumin and Westergren sedimentation rate; 5) abnormal proctoscopy and barium enema (The latter examinations are a minimum for patients over 40 and in younger patients with

symptoms of recent onset and intractable clinical illness. The proctoscopy is directed at excluding inflammatory changes and examining the stool microscopically for white cells and parasites.); 6) a pelvic exam should be carried out to exclude ovarian malignancy involving the colon and to rule out subacute inflammatory disease of the pelvic organs.

The presence of weight loss, progressive pattern of symptoms, occurrence in older age group and brief duration of symptoms with no previous psychophysiologic disorder should alert one to the possibility of another process. The symptoms of the irritable bowel patient can be identical to the patient who has partial obstructing rectosigmoid carcinoma except for the shorter duration of symptoms, associated blood, abnormal proctoscopic exam, etc. In addition, patients with the functional colon syndrome are obviously not immune to developing other gastrointestinal diseases and should be periodically re-evaluated. Following these patients serially will be important to provide support and identify new symptoms or variations of old symptoms that could suggest a new problem.

In addition, the presence of an identifiable disease process should not exclude the presence of an unidentified structural process producing the symptoms. Some patients with ulcerative proctitis will experience bloating and alternating diarrhea and constipation as part of their irritable bowel syndrome and this will make it difficult at times to separate which process is most active. Similarly, secondary spasm and pain in reflux esophagitis may be related more to associated depression and anxiety than the actual peptic inflammation. The persistence of symptoms during therapy in this situation may be related more to the treatment being directed only at the peptic component. Anxiety and depression are great amplifiers of symptoms as well as producers of symptoms.

Once alternative diseases have been excluded, education is the first step in treatment. The patient must have a clear understanding of the symptoms and the fact that structural differences are present even if unidentifiable by our studies. Pain, diarrhea and dysphagia are not real. Patients' anxiety regarding these symptoms and what they imply, i.e., fear of cancer, surgery or starvation, frequently adds to their current life stresses. The patient can frequently palpate distended bowel loops, will observe the abdomen to swell and may experience severe pain. If patients are taught that these alterations can occur as a result of focal changes in bowel motility, this begins to provide some explanation for their problem and will help relieve their anxiety.

Physician awareness of the importance of the placebo effect is also important. Multiple studies have shown that approximately 30-35% of patients will improve with placebo despite the nature of their illness. Medical and surgical procedures carried out in patients with irritable bowel syndrome frequently result in transient improvement only to have the patient return weeks to months later with relapse of the symptoms resulting in frustration for the patient and the physician. Surgery, in particular, has a powerful placebo effect and it is not uncommon for these patients to be relieved of symptoms for three to six months after surgery for adhesions, hernia repair, cholecystec-

tomy, etc. when the anatomical correction had nothing to do with the patient's original symptoms. It must be emphasized that a symptomatic improvement in response to a specific therapy does not confirm a specific pathophysiologic illness. It is apparent from studies carried out by Alpers in functional colon disorders and by Wells and Lustman in esophageal disorders that 72-83% of these patients will have specific psychiatric diagnoses compared with 18-31% of controls. These patients have structural abnormalities in their brain that are not yet identifiable by neuropathologists. Many patients may be involved in anxiety-producing situations that are limited in duration, and the symptoms may resolve as the anxiety subsides. It should be emphasized that any of the irritable bowel syndromes whether they are esophageal, gastric or colonic may occur in any of a variety of psychiatric diagnoses ranging from situational anxiety, depression, somatization disorder to phobic disorders. Each of these labels will carry a different prognosis and require different treatment although the bowel symptoms may be identical. Environmental stressors should always be looked for as precipitating factors. According to Alpers, depression appears to be one of the most commonly missed diagnoses by internists, an important diagnosis because it may be amenable to tricyclic therapy. Patients must be educated as to the potential role of stress in their illness and be helped in assuming responsibility for changing that part of their life. This might include behavioral tasks like making up a list of stress-producing situations and identifying which situation may be changeable. Regular exercise will also be effective in reducing general stress and relaxation therapy, including meditation and biofeedback, is often helpful. The patient will need to understand that the disorder will fluctuate depending on an ability to control the stress in his or her life. The evaluation of the role of stress will be difficult at times and will depend on the type, intensity and duration of the stress and the presence or absence of a support system in the environment. Psychotherapy will be appropriate for those motivated to pursue their stressors more thoroughly.

Treatment of the esophageal disorders should be directed at the mucosal inflammatory process and the specific environmental stresses as noted above. Specific relaxation of the muscle can be carried out using nitrites and calcium channel blockers. However, these agents are more effective in the primary muscle disorders. Anticholinergies and mild sedatives can be used in both esophageal and gastric disorders, but tend to produce disagreeable side effects and have never been shown in any control studies to be more effective than a placebo. The colon disorder group can be helped by providing more bulk including bran, Metamucil or high fiber diets which can help stabilize the bowel pattern and avoid either obstipation or diarrhea. We must understand that we are treating symptoms with these various programs and our goal should be to alleviate or reduce the causal factors where they are identifiable. In all irritable gastrointestinal disorders the symptomatic treatment should not supercede the identification and treatment of stress, the psychological component.

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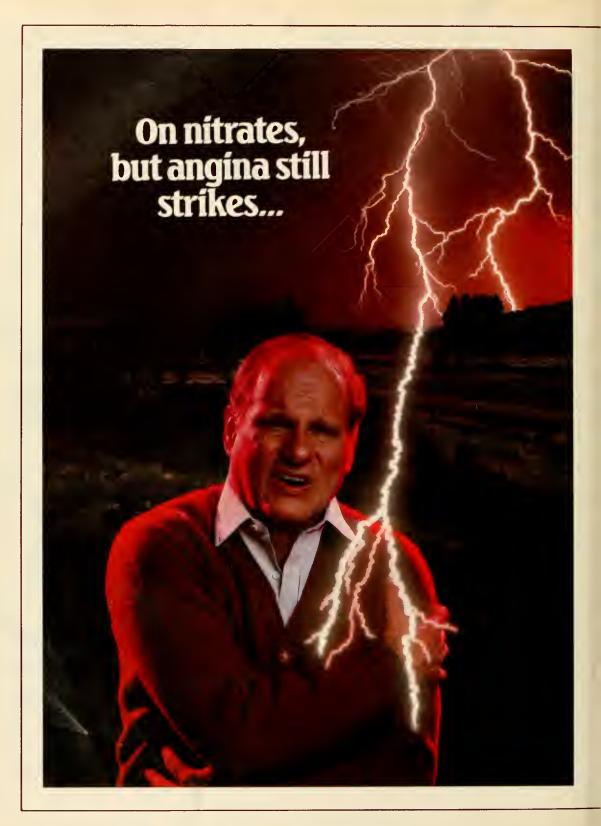
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# Multiple Organ Trauma Managed Cost Effectively and Nonoperatively

Milton D. Quigless, Jr., M.D.

REVIEW of recent surgical literature reveals a trend toward nonoperative surgical management of blunt traumatic injuries of the spleen and liver in selected cases. Blunt chest injuries have long been managed nonoperatively by frequent clinical assessment, including arterial blood gases, chest x-rays and expert clinical judgment. CT scanning has made exploratory intracranial neurosurgery for trauma a matter of historical interest. Management of a recent patient with closed head injury and significant chest, hepatic and splenic trauma illustrates nonoperative, cost-effective management.

A 33-year-old black man, a native of Kenya, had been in his usual state of excellent health until May 21 when he was brought semicomatose to the Rex Hospital emergency room shortly after his car had been hit by a truck.

Emergency room evaluation revealed normal stable vital signs. The patient was somewhat responsive in halting English to simple questions. His native language was found to be Swahili by the neurosurgical consultant, Dr. Carroll Mann, a noted big game hunter who speaks some Swahili. The patient had several abrasions about the scalp. His pupils were normally reactive to light, and he responded appropriately to painful stimuli. A deformity with tenderness suggestive of a fracture was seen at the left clavicle. The lungs were clear to auscultation, but there was moderate tenderness over the left rib cage. The abdomen was soft with normal bowel sounds and only minimal epigastric tenderness. There was no obvious evidence of extremity fractures with all extremities moving symetrically and equally.

Laboratory studies included an EKG revealing a T-wave abnormality thought to represent early repolarization. Arterial blood gases were unremarkable except for a PO<sub>2</sub> of 71 on room air. Electrolytes and M12 were normal. Hemoglobin and hematocrit readings at three hour intervals revealed a hemoglobin of 15.2 g/100 ml, hematocrit reading of 44; hemoglobin 15.6, hematocrit 43; hemoglobin 14.1, hematocrit 43. Urinalysis revealed 8 red cells per high powered field. X-ray studies included a chest x-ray revealing fracture of the mid shaft of the left clavicle with slight apical pleural thickening. There were fractures of the left fifth, sixth, seventh and eighth ribs at the mid axillary line. The aortic arch was not well visualized. A single view of the cervical spine was unremarkable.

CT scans included a contrast study of the aorta revealing

no obvious tear. CT scan of the chest revealed a small left pleural effusion. CT scan of the head without contrast was unremarkable. CT scan of the abdomen revealed a significant subcapsular hematoma of the right lobe of the liver and hematoma surrounding a fractured spleen. No obvious pancreatic injury was seen.

The patient was admitted to the surgical intensive care unit where his vital signs, neurological status, cardiac function, urinary output, and positive physical findings were closely monitored. Appropriate intravenous fluids were given. Analgesics were limited to codeine 30 mg intramuscularly every four hours so as not to distort the neurological findings. Serum amylase remained normal on three daily determinations. Over a four day period the patient's sensorium returned to normal except for amnesia concerning the accident.

Daily chest x-rays revealed accumulating left chest fluid such that thoracentesis on the third hospital day yielded 550 cc of bloody fluid which did not significantly recur on follow-up films. Computed tomogram revealed the subcapsular hematoma over the right lobe of the liver to be unchanged as was the perisplenic hematoma. Five days later, repeat scan revealed complete reabsorption of the right liver subcapsular hematoma and a more recognizable spleen as the irregularity had diminished, although the spleen was still surrounded by hematoma.

Serial complete blood counts revealed the hemoglobin to diminish to 10.0 on the third hospital day but this increased to 11.8 by day six without transfusion. The platelet count diminished to a low of 72,000 on day four but increased to 107,000 by day six.

During the hospital course, the patient's temperature ranged from normal to a high of 101.8 on intravenous Kefzol.

The patient was sufficiently stable by day three to be transferred from the intensive care unit to a private room where by the next day he was tolerating a soft diet very well. On May 28, the patient was discharged home on Tylenol #3 tablets to take as needed for pain and tetracycline 500 mg caps four times daily for pulmonary prophylaxis with instructions to return to Rex Hospital for repeat chest x-ray on June 2 and to be seen in my office on June 3.

Despite letters to all known addresses by registered mail with the slips indicating receipts of letters, despite advice to come to my office for followup evaluation when the patient would call me at home for advice concerning his condition, I did not see him again until he appeared at my office on July 15 seeking insurance form signatures. At that time he was found to have non union of his clavicle fracture, but was otherwise entirely well on physical examination. He subsequently failed to appear for his scheduled followup chest x-ray and laboratory studies.

#### Comment

It is interesting to note that the total charge by Rex Hospital for this patient's hospital stay amounted to only \$5,050.35. My fee was \$560. By contrast, another patient of mine who suffered blunt abdominal trauma after an automobile accident in 1983 underwent splenectomy at Rex Hospital because of hemorrhage requiring six units of blood prior to and during surgery. His cumulative hospital bill after one week was \$10,404.92 and his total bill for 14 days was \$11,944.62. My fee was \$1,225.

Computer search of the recent literature on blunt splenic, hepatic and abdominal injuries yielded four articles that I consider pertinent on splenic trauma, four articles on liver trauma and one article from the radiologic literature regarding computed tomographic scanning of the abdomen.

A two-year retrospective study by Kakkasseril¹ reported in 1981 that 21 of 29 children with splenic injury documented by scintiscans were successfully treated without surgery. Of the other eight patients, one died shortly after admission of associated injuries; seven underwent surgery, with four having splenectomies, two having partial splenectomies and one having splenorraphy. The indication for surgery was evidence of continued blood loss or free intraperitoneal air. The average hospital stay for the nonsurgical group was 13 days; those undergoing surgery required an average 20 day hospital stay.

Gerritsen and Madern<sup>2</sup> presented the conservative management of splenic rupture in four patients. They suggest that initial conservative therapy is warranted after scintiscan demonstration of splenic trauma, with laparotomy reserved for those with signs of hemorrhagic shock despite transfusions, increasing peritoneal tenderness or suspicion of concomitant damage to other peritoneal organs.

Shandling<sup>3</sup> reported in 1980 that of 75 patients found to have significant splenic trauma by scintiscan, only 21 underwent splenectomy. Of the 54 patients with splenic injury not requiring surgery, many required several blood transfusions. He specifically mentions that in his series

there were no cases of delayed rupture, and he found no correlation between the radiographic extent of the degree of splenic injury and necessity for surgery. Shandling states, "Just as a kidney stops bleeding, so does a spleen."

In the presumably less sophisticated circumstances prevalent in Papua, New Guinea, Hamilton<sup>4</sup> reports that 27 of 33 patients with suspected traumatic splenic rupture were managed nonoperatively over a six year period ending in 1982. Hamilton finds splenic preservation to be most important in his geographic area where malaria is endemic, as death from malaria is felt to be far more likely in the patient whose spleen has been removed.

Of 141 documented spleen injuries due to blunt trauma referenced above, nonoperative management was successful in 106 or 75% of cases (table 1). In each of the 34 operated cases conservative therapy was initiated, but laparotomy was made necessary by evidence of continued blood loss or evidence of injury to other intraperitoneal organs as indicated by free intra-abdominal air or worsening peritoneal signs. Initiating a conservative protocol for splenic injury rather than the kneejerk laparotomy reponse to a blood return on peritoneal lavage might obviate many splenectomies occurring, in the words of Shandling, when "bleeding recurs while mobilizing the spleen preparatory to removing it."

Trunkey et al5 reported the Parkland hospital series of 811 consecutive cases of liver trauma from 1963 to 1971. Of these cases, 167 resulted from blunt trauma and many of these had other associated injuries. All 811 patients underwent laparotomy. In the entire series, only two patients with "superficial linear capsular lacerations with no bleeding" escaped surgical manipulation of the liver. Both of these were blunt trauma victims. Seventy-nine of the blunt trauma victims required placement of drains, but no sutures. The remaining 86 patients required a variety of surgical manipulations including suturing, resections and debridements. It is likely that many of the 81 patients with blunt trauma to the liver requiring either no surgical manipulation or only drainage might have been observable by serial computed tomographic scanning and physiological monitoring had the scanner been available at the time these patients were seen.

DeFore et al<sup>6</sup> presented 1,590 cases of liver trauma in Houston, Texas from 1939 to 1974 with statistics almost identical to those of Trunkey during the latter half of the

Table 1
Literature Review — Management of Blunt Spienic Trauma

	Totai splenic injuries	No surgery	Splenectomy	Partial splenectomy or splenorrhaphy	Dled
1. Kakkasseril	29	21	4	3	1
2. Gerritsen & Madern	4	4			
3. Shandling	75	54	21		
4. Hamilton	33	27	6		
	141	106	31		

Houston series. They note that "many liver injuries will have stopped bleeding by the time the abdomen is opened, and may be controlled by simple suture or drainage alone." Computed tomograms and physiological monitoring could have cost-effectively prevented surgery in many of these cases.

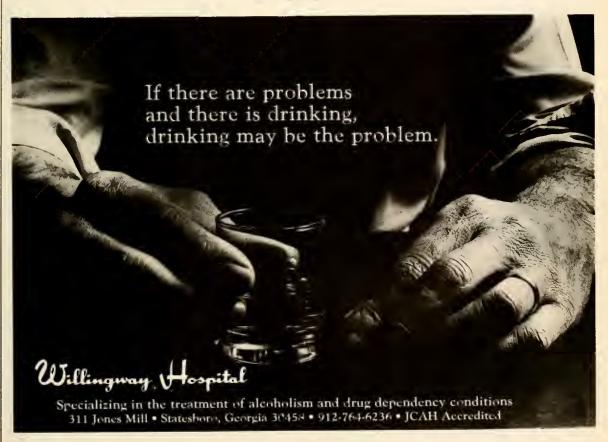
Lambeth and Rubin,<sup>7</sup> in 1979, presented four patients with blunt abdominal injuries resulting in intra-hepatic hematomas who were treated nonsurgically with "no untoward sequelae." Two of these patients underwent Gelfoam embolization of bleeding intra-hepatic vessels and two had no therapeutic intervention. Observation in all cases included close monitoring of liver function studies and hematocrit. They were observed by serial scintiscans, one by combination of CT scanning and ultrasonography. They concluded "... that nonoperative management of selected patients with intra-hepatic hematoma is reasonable and safe."

Berger and Kuhn<sup>8</sup> in 1980 reported the results of CT scanning of 23 children having suffered significant blunt

abdominal trauma. They found that "... the great superiority of CT over radionuclide imaging with respect to anatomic detail may make CT scanning the imaging method of choice when liver trauma is a strong consideration."

Meyer et al<sup>9</sup> reported their prospective study of 24 patients with blunt abdominal trauma found to have liver injury by CT scan who had no other injury requiring surgical intervention. None of these liver injuries required laparotomy, but close expert surgical evaluation and observation was necessary for proper management.

The case illustrated along with the brief literature review presented indicate that with the use of CT scanning and close expert surgical monitoring, many cases of blunt abdominal trauma can be managed nonoperatively in the presence of significant hepatic and splenic injury. Such management will usually result in significant cost savings and will often result in more rapid convalescence. The significant factor in conservative management of blunt abdominal trauma is the presence of a skilled surgical observer.



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# Disappearance of Psoriatic Lesions on the Rice Diet

Barbara Newborg, M.D.

OME time ago one of our Cardiology Professors stopped Dr. Kempner in the corridor and said, "I believe in the Rice Diet." Suspecting that his colleague wanted to tease him, Dr. Kempner replied: "You'd better tell me why." His colleague answered, "Every time my psoriasis flares up, I put myself on the Rice Diet until the psoriasis has disappeared. This occurs often within a short time."

The Rice Diet contains no more than 20 grams of protein — mostly derived from rice, 20-50 mg of sodium and very little fat with a relatively large percentage of linoleic acid. Figure 1 shows a comparison with a "so-called" normal diet.

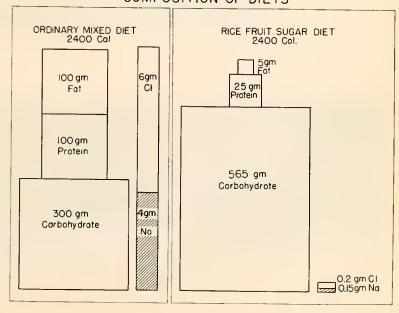
Results of the treatment with the Rice Diet in kidney, hypertensive vascular and heart diseases and diabetes were first published by Dr. Kempner in the forties.

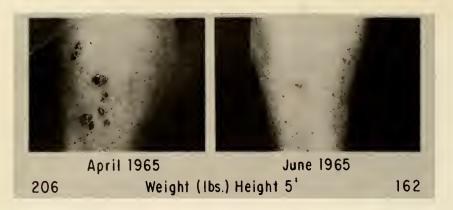
From the Department of Medicine, Duke University Medical Center, Durham 27710.

It soon became obvious that patients with psoriasis, being treated with the Rice Diet for any of the above-mentioned problems, showed a dramatic reduction in or disappearance of their skin lesion. Figures 2-5 illustrate these changes in four patients. None of these four patients had any systemic or other additional treatment while under observation here; local steroid treatment was either tapered off or discontinued in the patients who had been using it. Many of the patients whose psoriatic lesions improved during treatment with the Rice Diet had previously been treated unsuccessfully for years with systemic and/or local medications. There was not a single patient seen whose psoriatic lesions became worse on the Rice Diet.

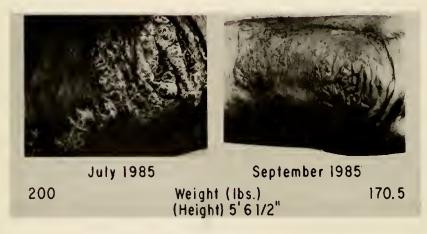
Whether the improvement in the psoriasis is due to an increase of a beneficial substance in the Rice Diet or to a decrease of a harmful one is not known. (We suspect it is the latter.) What is known is easily seen in figures 2-5, which show the improvement in the skin condition.

### COMPOSITION OF DIETS









## Disappearance of Psoriatic Lesions in 73 Year Old Man Treated by Rice Diet for 8 Weeks



April 18, 1984



June 13, 1984

# COMMENT

Claude S. Burton, M.D.

No one has found a *cure* for the skin condition psoriasis. Though our patients find this discouraging, we explain that with trial and error there is an excellent chance we will find a treatment to *control* the process. With appropriate supervision and treatment not even the hair-dresser can detect that my patients in fact have psoriasis.

I don't rely on a single treatment. Different approaches work for different people. Dr. Kempner and Newborg's anecdotal cases convince me that the Rice Diet should be added to the dermatologist's armamentarium, especially if the patient is obese, diabetic, or hypertensive.

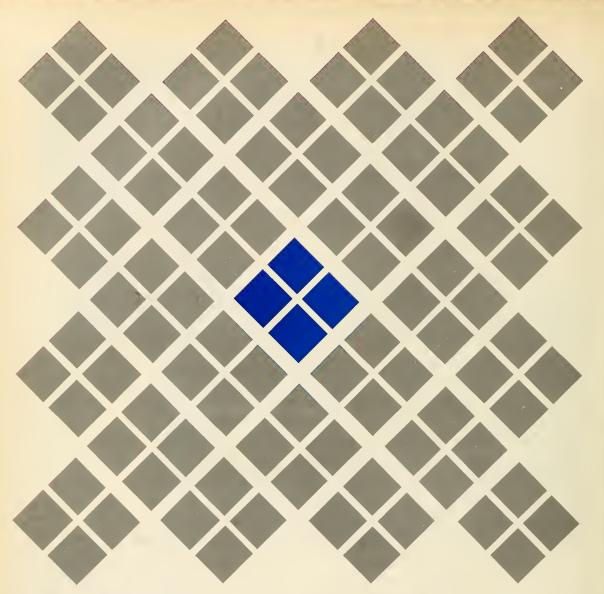
I cannot explain how the Rice Diet works in the treatment of psoriasis. Prostaglandin profiles are diet responsive and, based on early prostaglandin studies in psoriasis, a new enthusiasm for dietary therapies is emerging, especially those rich in EPA (eicosapentanenoic acid — an

unsaturated fatty acid prostaglandin precursor found in the flesh of many cold water fishes and now available from health food stores as MAX-EPA, thought to be the reason eskimos have such a low incidence of heart disease). Drugs that interfere with folate metabolism and virtually any agent that inhibits DNA or protein synthesis are effective at controlling psoriasis. One can imagine that the Rice Diet might have influences in all of these areas. Certainly, further clinical and laboratory investigations are warranted.

The Kempner diet excels in the treatment of heart and kidney disease, hypertension, diabetes and obesity. All of these illnesses limit choices of therapy for psoriasis and vice versa. For example, beta-blockers often flare psoriasis. Fatty infiltration of the liver in diabetics and obese patients may limit the utility of methotrexate therapy. For psoriasis patients with such comorbid conditions, the Rice Diet might be the best first-line approach.

We hope we will soon learn if all psoriasis patients respond to the Rice Diet and if this approach will be useful for non-obese psoriatics.

From the Divison of Dermatology, Duke University Medical Center, Durham 27710.



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# Fat Embolism Syndrome Without Adult Respiratory Distress Syndrome

Michael J. Bolesta, M.D.

AT embolism syndrome is a complex derangement of homeostasis most often associated with long bone fractures, but it can also complicate multiple nontraumatic conditions. The classic presentation consists of confusion, dyspnea, and petechiae; patients often present in acute respiratory distress. A less common presentation is illustrated by two patients recently treated at Duke University Medical Center.

#### Patient 1

A 28-year-old man sustained bilateral closed tibial and fibular fractures when a stack of sheetrock fell against him at a construction site. He was admitted to his local hospital on the day of injury and treated with manipulative reduction and cast application. The day after injury he complained of dyspnea, became agitated and had transient petechiae. Coma rapidly ensued and he was transferred to Duke. In the emergency room he was unresponsive to verbal but partially responsive to painful stimuli. There was extensor rigidity. Temperature was 38° C. On 100% oxygen by face mask, his PO2 was 110 mm Hg. He was placed in the intensive care unit, intubated and monitored. Oxygen was continued and his PO, tension gradually normalized. Sedation was required for agitation during the first 48 hours of hospitalization. He was extubated at this point and over the course of one week his neurologic status improved to normal. Approximately one week later he underwent manipulation of his fractures and application of casts without change in sensorium. Serial chest radiographs remained normal throughout his hospitalization.

A 28-year-old man was caught in a belt drive of a large machine and suffered a comminuted right subtrochanteric femoral fracture, midshaft left femoral fracture, open com-

and placement of traction pins. Intraoperatively there was a single dip in his oxygenation but this resolved spontaneously; postoperatively he was easily aroused and neurologically normal. Approximately six hours postoperatively there was an abrupt change in his mental status. He became comatose and manifested extensor rigidity. Pupils were reactive, reflexes were in-

minuted left tibial fracture and a nondisplaced left medial

malleolar fracture. There was no evidence of intoxication

or head injury. Within 10-12 hours he was transferred to

Duke for further evaluation and care. He was taken to the

operating room for irrigation and debridement of his wounds

creased and plantar stimulation produced extensor responses. His PO<sub>2</sub> was 59 mm Hg on 30% oxygen by face mask. A repeat determination while on oxygen showed his PO<sub>2</sub> to be 90. Throughout the remainder of his hospitalization, his oxygenization remained normal. Serial chest radiographs showed normal lung fields. Computerized tomogram of the head showed no mass lesion or intracerebral hemorrhage. Ventriculostomy was performed on two occasions, yielding normal intracerebral pressures.

His coma lasted two and a half weeks and was associated with profound extensor rigidity. Over the ensuing month there was gradual clearing of mental status with resolution of pathologic reflexes and return to normal neurologic function.

#### Discussion

The clinical diagnosis of fat embolization is one of exclusion. The presence of extensive trauma, the time of onset of neurologic symptoms and the fall in oxygen tension favor this diagnosis. No other disease process was discovered in these two patients.

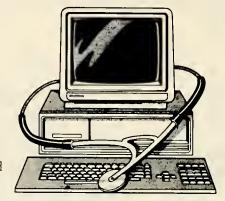
Fat emboli present complex and difficult problems in diagnosis and treatment. This variant with predominantly neurologic signs and a minimum of lung involvement is of interest. I hope other doctors will let me know about other unusual variants that they have encountered.

From the Division of Orthopaedic Surgery, Duke University Medical Center, Durham 22710.

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# North Carolina Medical Journal

Features for Patients

May 1986

# NORTH CAROLINA PHYSICIANS TALK TO THEIR PATIENTS

## Fertility Surgery

Jamil A. Fayez, M.D.

## Common Questions About Infertility

- What is infertility? Most doctors define infertility as the inability to conceive a pregnancy after one year of trying, or inability to carry pregnancies to a live birth.
- 2. How many people are affected in this country? At least 12 million people are involuntarily childless at any time. This represents one in every six couples of childbearing age.
- 3. What are the reasons for infertility? The general causes involve a femole problem in about 60% of cases, o male problem in about 40% of coses and combined problems in about 30%. At least 10% of infertile couples have no known cause. A great deal of research is now underway to find an explonation for unexplained infertility.
- 4. Can infertility be treated? Yes.
  Successful treatment leads to one
  or more pregnancies in 50-60%
  of cases. However, it is vital to get
  a reliable specialist and hove a
  thorough and proper investiga-

tion. Most major medical centers have consultants who are board certified in endocrinology and infertility and who are recognized as competent specialists in this field.

#### Common Myths About Infertility

- Infertility is o female condition. Not true. The mole is offected in almost 40% of the cases. It is essential that both the man and the woman get tested for infertility.
- Infertility is oll in the head. Wrong!
   It is real and can be diagnosed as
   o physical or hormonal problem
   in 90% of cases. The feelings of
   stress and frustration ore the result of being infertile, not the
   cause.
- Go odopt a child, then you'll conceive. Wrong again! First, adoption is more difficult now than ever. Second, people who have adopted become pregnant in only 5-10% of cases, the exact same percentage as those who do not adopt.
- In this over-populated world, infertile people have no right to try to get pregnant. Wrong! Zero Population Growth is based on 2.11

children being born to each couple of childbearing age. The choice to be fertile and to parent is o basic human right.

#### Services

Telephone counseling is available os fallows:

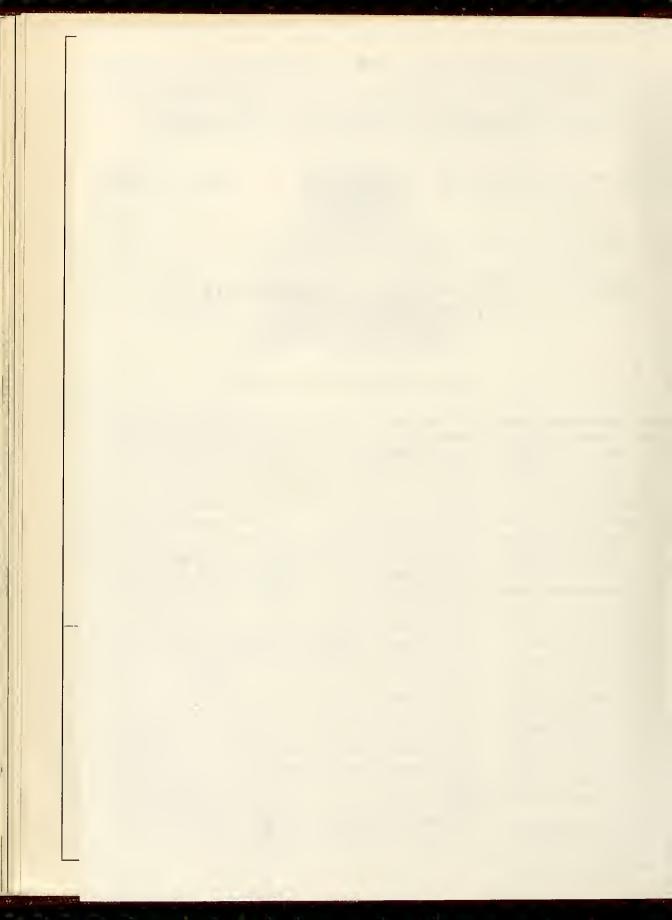
Monday	8:30 p.m4:30 p.m.
Tuesdoy	8:30 p.m4:30 p.m.
Wednesday	8:30 p.m4:30 p.m.
Thursdoy	8:30 p.m4:30 p.m.
Friday	8:30 p.m4:30 p.m.

You may coll our infertility and endocrinology nurses, at the following numbers:

919/748-4141 919/748-2901

Referrol: You may be referred by your physician to our Endocrinology and Infertility Clinic or, if you desire, you can call our nurses directly for counseling and advice. Our nurses help you assess your needs, then make appropriate recommendations to the best ovailable medical care; to individual counseling; or to an alternative such as adoption or artificial insemination.

From the Department of Obstetrics and Gynecology, Bowman Gray School of Medicine of Wake Forest University, Winston-Salem 27103



#### Infertility Work-up

You may need to have one or more of the following tests to find out your problem and treat it. This infertility work-up usually takes two or three months to be completed. After the completion of your work-up, you and your husband will have a counseling session with your doctor to discuss the results and the recommended treatment.

1. Basal Body Temperature Chart (BBT): Put the thermometer under your tongue for five minutes the first thing in the morning prior to any morning activity. Record your temperature on your BBT chart immediately. This will give us an idea whether you ovulated or not. We match these chart recordings with your endometrial biopsy to find out if there is any defect in your ovulation. Therefore, you should take your temperature properly. Circle the days you have intercourse.

Bring your Basal Body Temperature chart with you at office visits. Always use the Basal Body Temperature thermometer, NOT the regular one. When you start a new cycle, start recording your temperature on a new block of your chart where day one marks the first day of your period. If you take any medication, write the initial of this medicine on the day you use it. Do not take your temperature beyond the 35th day of your cycle. If you do not bleed by day 35, call the infertility and endocrinology nurse for advice.

- 2. Hysterosalpingogram: This is an x-ray of your uterus and tubes. It tests the shape of your uterus and whether your tubes are open. It is done during the first half of your cycle after you stap bleeding. A normal result means your uterus is normal in shape and your tubes are open. However, it does not exclude adhesions or scar tissue around the tubes or ovaries.
- 3 Postcoital test: This is the afterintercourse test which is dane 6-12 hours after intercaurse. It is done on the day af your ovulation or one or two days prior to that. Your husband

should abstain from sex at least 48 hours prior to the test. A good result means that your husband's sperm is probably normal and that the secretions of your cervix are good. It also means that your husband's sperm and your mucus are probably compatible.

- 4. Endometrial biopsy: This is performed during the last three days of your cycle and shows if you are ovulating normally. If the dates on your 8BT chart match with the biopsy, then your ovulation is adequate.
- 5. Semen analysis: The husband should abstain from sex 48-72 hours prior to giving his semen specimen. The specimen should be collected in the infertility lab area. The husband will be provided with a private area for masturbation.
- 6. Laparoscopy: This is a procedure in which the doctor makes a surgical incision in the umbilicus and inserts a special instrument into the abdominal cavity which allows him to see your female organs. Through a second small incision in the pubic hair area, he can perform simple surgical operations. Laparoscopy is sometimes done only for the purpose of diagnosis, which means that it is not being done for treatment of any disease or condition, but only to help the doctor find out if any disease is present.

During laparoscopy, your doctor will try to remove all adhesions, scar tissue or small cysts that may be a couse of infertility. This operation through the laparoscope will be done only if it can improve your fertility potential and only if it does not cause any major risk to you.

Laser laparoscopy may be used to remove endometriosis or cut scar tissue from your pelvis. This may require a third very small incision a few centimeters above your pubic hair.

No major procedures will be performed through the laparoscope. 8ig problems should be handled by major surgery. Laparoscopic findings with appropriate recommendations will be discussed with you and with your husband on the same day of surgery before your discharge from the hospital.

Complications are minimal, if any. However, they may occur and your doctor will discuss them with you. Slight shoulder pain may persist for 12-24 hours after surgery. All you need to do is take two aspirin tablets every six hours when needed.

Usually you go home on the same day of surgery if you wish and if your doctor finds that appropriate or you may prefer to stay overnight if you are not fully awake and alert.

Your doctor would like to see you in the office three weeks after your discharge from the hospital for reevaluation and advice.

7. Hysteroscopy: This surgical procedure involves the administration of a clear transparent fluid into your uterus. The fluid distends the uterus and separates the walls so that the hysteroscope views the details of the inside of your uterus. Scar tissue, polyps or fibroids can be seen and possibly removed through this procedure. Even a septum (partition) inside your uterus can be excised through the hysteroscope. Your physician usually discusses the details of these procedures and any possible complications with you.

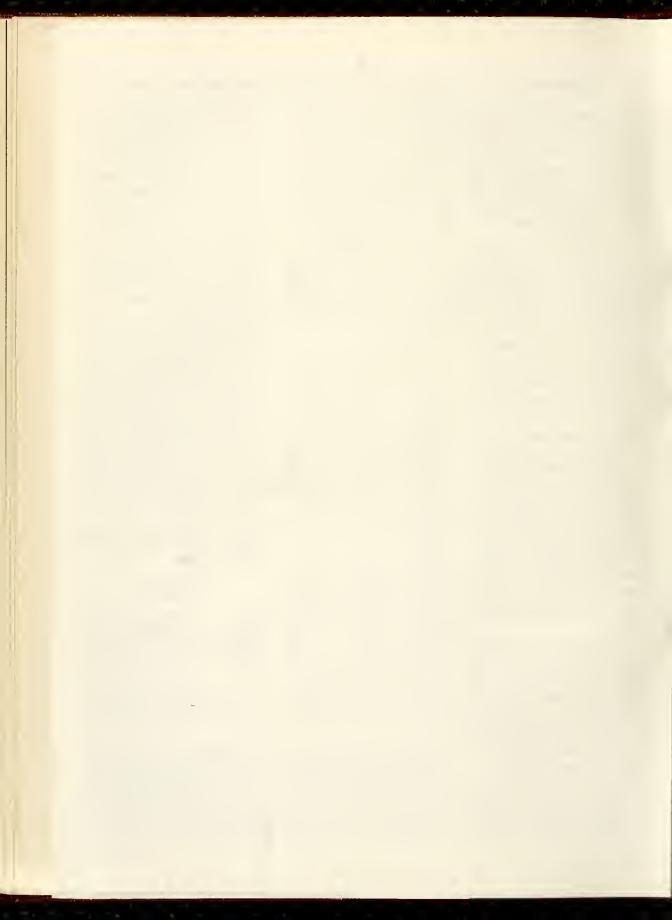
If you have any questions, you may call the infertility nurses at the following numbers:

#### 919/748-4141 919/748-2901

Monday	8:30	p.m4:30	p.m.
Tuesday	8:30	p.m4:30	p.m.
Wednesday	8:30	p.m4:30	p.m.
Thursday	8:30	p.m4:30	p.m.
Friday	8:30	p.m4:30	p.m.

You may cancel your postoperative appointment and any necessary instructions will be given to you by phone.

8. Tuboplasty: If your doctor has determined that you are infertile and that the reason for this condition is because your fallopian tubes are not open, you may need to undergo a tuboplasty procedure. The fallopian tubes are the ducts in the female pel-



vis which allow the egg produced by the ovaries to reach the uterus or wamb. When these tubes are closed, it is unlikely that the male sperm could come in contact with the female egg ta result in pregnoncy. The tuboplasty operation will not help you physically. It is only performed on those wamen who have a strong desire to become pregnant. This is because the averall success rate for the operation guoted in most medical literature is low, varying fram 5 to 65% depending on the type of surgery perfarmed. In other words this aperotion will not avarantee that you will become pregnant. Furthermore, as in any operation, there exists the possibility of complications. For the best possible results, the microscope and microsurgical instruments will be used to repair your tubes. This is the most advanced technique available. If necessary, the laser will be used to repair the tubes.

Fallopian tuboplasty requires a surgical incision in the lower abdomen in the area of the pubic hair. The incision will be short, about 5 inches, and will be hidden by the hair so that it will not show during swimming, etc. Possible complications will be discussed with you and your husband in detail.

All the details af surgery performed on you as well as pertinent odvice and recammendatians will be fully discussed with you and your husband before your discharge from the hospitol.

You may go hame within 2-5 days depending on how well you do fallowing surgery. You can expect to be out of wark 2-5 weeks unless your doctor states otherwise.

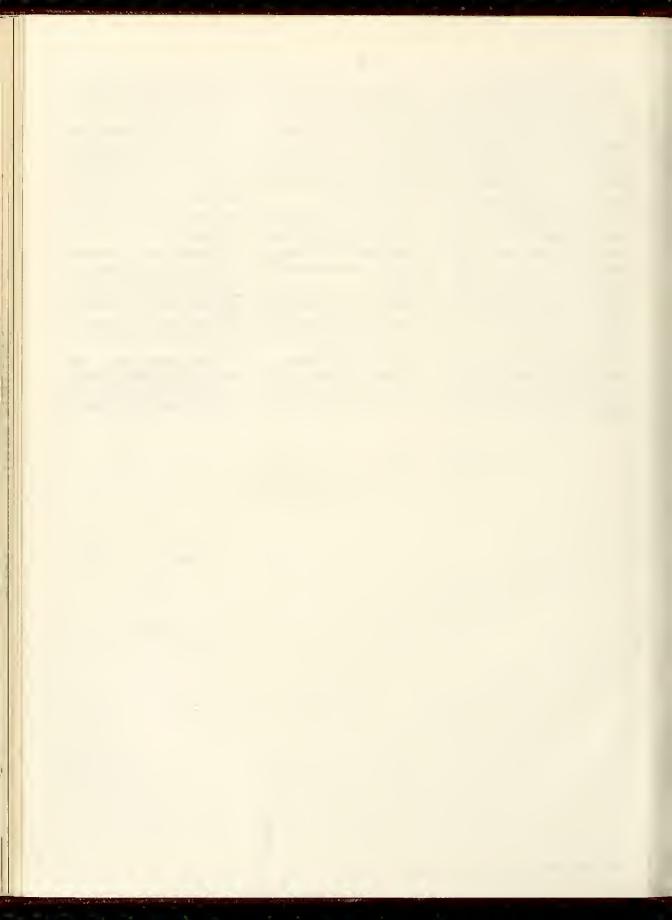
Your doctor would like to see you in the office three weeks after your discharge from the hospital for reevaluation and advice. You may can-

cel your pastaperative visit and all necessary instructions will be given to you over the phone.

9. Sperm antibodies detection test: Very few patients in whom we suspect the problem of sperm antibodies may need this test. The wife or the husband or both may have sperm antibodies that interfere with adequate sperm function by rendering sperms immobile or by their clumping together.

10. Pergonal: This is in the form of an injection that has two potent hormones to induce ovulation. Close observation by ultrasound and other means is mandatary to avoid the risk of multiple births and overstimulation. The doctor will discuss this with you.

11. Laser Surgery: We use laser through the laparoscope to treat endometriosis and pelvic adhesions without any need for major surgery.

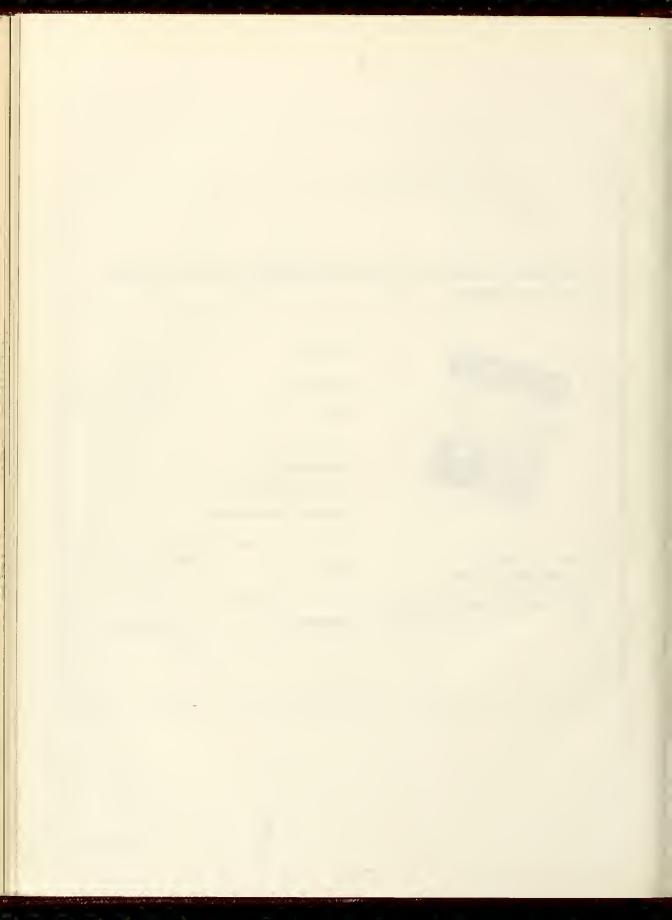


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## Quinine Poisoning: Rage Against the Dying of the Light

Ronald B. Mack, M.D.

ANY of us were brought up to believe that poets and M readers of poetry were strange, effete and somehow tuned into different frequencies that we were not privy to and would not want to be anyway. College changed all that for me. The Jesuit university that opened my mind to the wonders of the literature of Western Civilization demanded that all pre-med students take humanities courses, i.e., the theater, poetry, English literature, etc. Nonsense we said, we have just come home from WWII and needed to get on with our lives and change the world and could do so without the need of rhyming biochemical formulae. Nonsense said the learned priests, we aim to educate the whole man. (It was an all male school in those days, thank goodness - the less distractions the better for men whose contact with women in the preceding few years was limited to pin-ups and USO troupers.)

We soon discovered that "real men" can read poetry (and write it as well) and enjoy it — "real men" can certainly read Dylan Thomas. This Welsh man of letters was a fairly tough character, a street kid with little formal education but with the ability to write beautiful mystical poetry and prose in his short lifetime of 39 years. (The poet died in New York City in 1953 from an attack of delirium tremens.)

definition tremens.)

Dylan Thomas' best poem, in my opinion, was the one that begins:

"Do not go gentle into that good night.
Old age should burn and rage at close of day;
Rage, Rage against the dying of the light..."

This poem was written by Thomas to his father, and in the poem he advises his father to be bold and rebel against a quiet acceptance of death. This is unquestionably a beautiful, thought-provoking piece of work and it also tripped off in my mind those poisons that can cause blindness, quinine for example.

Quinine poisoning is not very common anymore in this country, obviously because not as much quinine is being used. When was the last time you saw a case of malaria in your office or emergency room? However, the use of the drug for the treatment of nocturnal leg cramps is increasing and one can foresee an increase in problems related to this drug — either accidental ingestion or purposeful overdose by someone who is depressed enough to seek

permanent relief from their demons. Quinine is currently quite popular as an adulterant for heroin (both products have a similar bitter taste and it would be difficult for the unsophisticated buyer to taste the difference). The drug has had a long history of use an an abortifacient.

This drug has been in continuous use for centuries, which makes it unique in modern medicine. It is the chief alkaloid of cinchone which, as you recall, is the bark of the cinchona tree found in South America. The first written report concerning quinine's use can be traced to a book written in 1633 and published in Spain by a Peruvian monk. He called cinchona the "fever tree" because, he alleged, when given as a decoction it "cures the fever and tertians" (possible reference to malaria). The first official recognition of cinchona occurred in 1677 when it was included in the London Pharmacopoeia. In 1820, scientists (Pelletier and Caventon) isolated quinine and the rest is history.

Quinine affects a large number of different biological systems and has been referred to as a "general protoplasmic poison." It is quite toxic to many microorganisms such as plasmodia, spermatozoa, many bacteria, trypanosomes and yeasts. Local responses to this drug include sensory nerve stimulation followed by paralysis as well as abdominal pain, nausea and vomiting. If the drug is given subcutaneously or intramuscularly the results can be very painful indeed and sterile abscesses can ensue. Intravenous use can lead to thrombosis of the injected vessel.

In therapeutic systemic doses, quinine has a long history as an antimalarial drug; it acts mainly as a schizontocide. (Now there's a new word for today. Saying it rapidly three times may become a new roadside test for sobriety.) Now a schizont, in case you forgot, is a sporozoan trophozoite that reproduces by producing a varied number of daughter trophozoites or merozoites. This drug also acts as an antipyretic and has analgesic qualities. There is very little chance, however, that it will replace aspirin or acetaminophen although historically it was used against many forms of febrile illnesses. Quinine acts very much like its isomer quinidine in reference to the cardiovascular system, i.e., relatively powerful direct effects on most cardiac cells as well as drug-induced alterations of autonomic regulation of the heart and electrical properties of cardiac cells. This drug has the ability to lower blood glucose concentrations probably by stimulation of insulin secretion.

Quinine's effect on skeletal muscle is of great concern to us here because the most common way that most of us

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will encounter the drug, toxicologically speaking, will be to give advice about an overdose resulting from someone taking someone's quinine that is being used to combat nocturnal leg cramps. This drug increases the tension response to a maximum stimulus delivered directly to the muscle or through a nerve. It also increases the refractory period so that the response to tetanic stimulation is ameliorated. Furthermore, and this is good news to leg cramps sufferers, the excitability of the motor end-plate area decreases in such a way that repetitive nerve stimulation to acetylcholine is decreased; in fact, it can apparently antagonize the action of physostigmine on skeletal muscle as effectively as curare.

Quinine is readily absorbed when given orally mainly in the upper small bowel. Try not to give this drug subcutaneously or intramuscularly because the pain and local tissue damage makes these routes generally likely to make you an ogre in the mind of the patient. Peak plasma levels are achieved one to three hours after a single oral dose. About 70% of the drug is bound to plasma. The V<sub>D</sub> (volume of distribution) is  $1.8 \pm 0.4$  liters/kilogram, although wide variation is possible. The T-1/2 (half-life) can also vary widely with  $11 \pm 2$  hours given as a current mean; it is shorter in children.2 The liver primarily, but also the kidney and muscles, metabolize three-fourths of an ingested dose with only 5% excreted unchanged in the urine. The metabolites are excreted in the urine and it might be useful to remember that the renal excretion of quinine is doubled when the urine is acidified compared to when the urine is alkaline.

An overdose of quinine leads to a syndrome with a very unforgettable name — cinchonism — which consists of nausea, vomiting, tinnitus, deafness, vasodilation, headache and vertigo. More serious toxicity can result in cardiac arrhythmias, hypotension, convulsions, coma and death. The most spectacular clinical feature of this overdose is the visual disturbances of which sudden loss of vision is the most dramatic manifestation — literally the "dying of the light." Other ophthalmologic clinical features include diplopia, altered color perception, photophobia, scotomata, dilated pupils and blurred vision. The cardiovascular manifestations seem to be related to the level of the drug in the myocardium. You could see abnormalities as depression of AV or intraventricular conduction, cardiac contraction and hypotension as well as prolongation of the QRS complex or QT interval, ST depression (with or without T-wave inversion). In some worst case scenarios, ventricular tachycardia or fibrillation can occur which can lead to a trip to that Big Emergency Room in the Sky. If the patient is a pregnant woman who gets too much quinine, accidentally or on purpose, the result can be premature labor or abortion because of the oxytoxic action of the drug. This explains why the drug was used for so many years as an abortifacient. The fatal oral adult dose of quinine is about eight grams; in small children the fatal dose can be less than 20 mg/kg.

The treatment of quinine overdose is in some ways standard and in other ways very controversial. Gastric emptying is indicated. Quinine has an anticholinergic ef-

fect and thus gastric emptying can be delayed; it is probably worthwhile to attempt gastric decontamination even after the usual four hours post-ingestion. The symptomatic treatment of other damaged organ systems is fairly noncontroversial, i.e., hypotension treated by IV fluids and norepinephrine if necessary; cardiac abnormalities can be treated with lidocaine, phenytoin or transvenous pacemaker if clinical features warrant. Over the years many methods have been tried to increase the excretion of quinine but no one method is very efficient in this regard. Forced acid diuresis with drugs like ascorbic acid should really make a difference but the amount recovered in the urine is probably not clinically significant. Similarly, hemodialysis, peritoneal dialysis and hemoperfusion do not seem to increase clearance enough to be worth the effort although some authors allege that the latter method seems to improve the clinical condition of the patient.

We need to focus (a bad pun) on the eye findings in quinine poisoning because of the controversy surrounding the treatment. Death is unusual in this overdose and the only long term adverse effect is visual impairment, usually peripheral visual field constriction with optic atrophy. The sudden loss of vision can occur anytime in the first 24 hours after overdose. The initial clinical sign is usually dilated pupils and loss of acuity. Changes in the retina may not appear for one to three days and are apt to be retinal edema, vessel narrowing, and pallor of the disc. There is a controversy raging about the pathophysiology of quinine blindness. The amaurosis can be caused by a direct toxic involvement of the retina or vasoconstriction of the retinal artery or both (or neither, I suppose). In my opinion, the most innovative treatment used against quinine-induced blindness is stellate-ganglion blockade. The purpose of this procedure is to relieve retinal ischemia. The results of this procedure are mixed and in some recent articles the authors suggest that supportive care is still the way to go and that stellate ganglion blockade is not the answer.3, 4 Fortunately most patients recover their vision even after a total loss of sight although restriction of peripheral visual fields may be the end result.

Don't be surprised if you are called upon to treat a quinine overdose. Its use in treating nocturnal leg cramps is quite popular. We are not only talking about prescription drugs such as Quinamm (each tablet has 260 mg of quinine sulfate) but an over-the-counter television advertised product, Legatrim (130 mg of quinine sulfate). According to the Consumer Product Safety Network, one-third of poisonings in preschool children due to prescription drugs occur in the home of the grandparents. Young people also can go into "that good night" and not always willingly or gently.

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## Thyroid Glands, Bottle Corks, and Pemberton's Sign

M. Andrew Greganti, M.D.

THORACIC inlet obstruction by retroclavicular thyroid masses has been compared to inserting a cork into the neck of a bottle. Patients present with respiratory distress and facial suffusion after neck flexion or elevation of the arms, maneuvers that push the "cork" further into the "neck of the bottle." Although this clinical syndrome is well documented, its recognition may be delayed by the retroclavicular location of the enlarged gland and by the short, obese habitus of some of the patients. Such was the case in a patient who came to our emergency room with dyspnea.

For 1 or 2 months the patient, a 61-year-old woman, had intermittently awakened from sleep with a choking sensation and a cough productive of small amounts of white sputum. On the night of admission, her cough was more productive than before and was associated with dyspnea followed by syncope. After regaining consciousness she was brought to our emergency room. Only rhonchi were heard on chest examination, and there were no abnormal cardiac findings. Her electrocardiogram showed an old inferior myocardial infarction, and mild cardiomegaly was noted on her chest radiograph. The emergency room physician concluded that the patient probably had paroxysmal nocturnal dyspnea secondary to congestive heart failure and began furosemide 40 mg daily. On clinic follow-up, she had improved but did complain of intermittent choking sensations and episodes of wheezing.

Three months after her initial presentation, the patient experienced a recurrent episode of severe dyspnea while leaning over a sink to wash her hair. The symptoms cleared quickly when she stood erect. Having her raise her arms above her head produced marked inspiratory stridor and some facial suffusion. Her short neck and an anterior fat pad prevented adequate palpation of the thyroid gland; however, no glandular enlargement or tracheal deviation was appreciated.

A mass deviating the trachea to the right on barium swallow was confirmed on echogram as a sonolucent 4 by 2 cm cystic lesion which was compressing the trachea midway between the thyroid cartilage and the sternal notch. On thyroid scanning, the gland appeared normal but deviated to the right by the mass. As expected, pulmonary function testing confirmed that both inspiratory and ex-

piratory flow volume loops were compatible with flow restriction secondary to a fixed obstruction.

At surgery the patient had a large hemorrhagic thyroid cyst originating in the left lobe and extending toward the thoracic inlet. Following excision of the cyst, the trachea immediately returned to the midline. Postoperatively, she did very well without recurrent cough, wheezing, dyspnea or sputum production.

The patient represents several important clinical features of upper airway obstruction produced by thyroid masses. Symptoms and signs of obstruction are probably more common than usually appreciated. In one study of patients with euthyroid goiter, nine of 20 had a history of shortness of breath on exertion and a choking sensation, usually insidious in onset.<sup>2</sup> Findings of upper airway obstruction were detected in seven of the 20 by roentgenography, in 12 by flow volume loop, and in 16 by a combination of flow volume loop and roentgenography.

Although occurring in the setting of intrathoracic goiter,3 obstruction is more likely and more acute in onset when caused by retroclavicular entrapment of a large benign goiter.1 Anatomically, this makes sense when one considers that the thoracic inlet is a relatively narrow space defined by the clavicles, sternum, and vertebrae. There is little additional room for descent of an enlarging thyroid cyst or nodule. In contrast, a substernal goiter has considerably more space in which to expand because the trachea curves dorsally below the thoracic inlet, leaving room anteriorly. This relationship becomes particularly critical when there is rapid expansion or wedging of a thyroid cyst into the inlet following acute intracystic hemorrhage1,4 or following rapid changes in gland position, as may occur from flexion of the neck during sleep. Blum's use of the term, "thyroid cork," seems very appropriate in these situations. In retrospect, such a scenario explains our patient's initial presentation to the emergency room following a syncopal episode.

Early diagnosis of tracheal obstruction at the thoracic inlet is best accomplished on physical examination by pushing the "cork" into the "neck of the bottle." Pemberton described how to do so by raising the patient's arms vertically above the head immediately adjacent to the face. 5.6 As in the case of our patient, a "positive" result is associated with inspiratory stridor and facial plethora due to tracheal constriction and venous inflow obstruction. The symptoms and signs are exacerbated by neck flexion and decreased by neck extension. Using this simple ma-

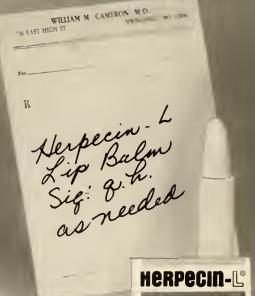
From the Department of Medicine, University of North Carolina School of Medicine, Chapel Hill 27514.

neuver at the time of our patient's initial presentation may have led to the correct diagnosis.

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### Essence of a Stroke

Perry Glen McLimore, M.D.

ANY times I forget, not what my job entails for me, but what it entails for the people I come into contact with: patients. Just when I feel secure that my emotions have been properly suppressed, an individual appears who breaks this fragile impassiveness. Suddenly the frail, frightful feelings that I had laboriously attempted to dissolve congeal. I am left with thoughts of regret but also with a sensation of satisfaction, having had the opportunity to know and grow with my subject. Undoubtedly, I learn a great deal about the disease process. More important, though, I learn to feel; I learn how these encounters alter my impression of the sick and what taking care of people means. I am taught inspiration. What follows is one example of these humbling experiences.

Internship means patients and Mr. Inman was only a patient who, after filtration through rungs of stationery, was randomly assigned to my ward - a capricious, panoramic commune where he was to become my patient. another patient; one to be worked up, written up, and presented to my mentors in one short day. Another name added to an already overwhelming list of responsibilities. Entering his room, I introduced myself in a somewhat pretentious manner, offering little doubt about the fact l was his "doctor." He politely acknowledged my title but seemed concerned about my youth. His attire and the neat manner in which he had arranged his belongings suggested that Mr. Inman was a formal, independent person. With this in mind I performed the subtle gestures to establish territorial rights, trying not to expose my insecurity. A few well-rehearsed phrases helped relinguish his uneasiness as well as my own. Activities outside, seen through a corner window, provided a comforting distraction, and a spontaneous conversation soon developed. I felt a working relationship had been established. That initial barrier of apprehension was successfully scaled. With learned intent, I began my work.

As for Mr. Inman, he was not particularly distinguished in appearance. A youthful quality existed about his eighty year old face that made him likable. Sitting on the edge of the bed, he was obviously nervous. An amputated right thumb continuously caressed and explored his left hand. The wrinkles on his pale face formed deep grooves, which became more prominent when he smiled. Combined with a matted silver-gray border of hair, they created a distinctive style of headdress. His personality seemed frail, although my encounter with this aspect of the man was

too brief to elaborate on. A thin man with a wasted appearance, he talked and gestured in such an energetic manner it made me lighthearted. His deep, stern voice reverberated about the dim room and left small doubt of the honesty of his answers. Socially clean relative to the surrounding population, he had not smoked for twenty years or heavily indulged in alcohol.

An inactive wife and daughter stood close by, ever inquisitive but humble nevertheless. Their questions were appropriate but not challenging, and I sensed the development of their trust. Both expressed faith in being in the "great" hospital. My face blushed at the remark, feeling important but frightened: it reminded me of the burden of responsibility such confidence meant. Anyway, the faces of concern had grown smiles and I enjoyed the gratification. So went my first engagement with Mr. Inman and his family. The task of question and examination was performed. After reassurance, I went my way feeling secure in the knowledge that Mr. Inman had been properly processed, packaged, and prepared to allow the machinery of medicine to work.

The next day was uneventful. When possible I would stop and chat with Mr. Inman. He lacked much formal education, but his intelligence and his pragmatism offered a haven from the constant decisions that flooded my life on the ward. His stories and experiences were entertaining and frequently thought-provoking. In just two short days I found myself confiding in him. His empathy was genuine, his advice not threatening, as if he had braved similar stresses to those I was currently undergoing. I thoroughly enjoyed these conversations.

The following afternoon I was summoned to his room. Upon arrival I found Mr. Inman perched from floor to bed, motionless. His eyes, once active, once observant, were fixed on a dust ridden floor. The wrinkles, which had given Mr. Inman a show of nobility, hid in the sagging skin covering his expressionless face. The right side of his body was flaccid. There was no response to his name. As I helped place him back into the bed, my eyes began to swell. An urgency to leave his room overtook me. Galloping down the busy hall, I grasped his chart. Fervently l searched. Had I missed something or prescribed something to cause such an event? A tear smudged the ink from a previous note. There was nothing, no explanation. My anger intensified. Why had Mr. Inman done this to me? Fear disabled my actions. Tragedy has a deplorable quality of being able to override all learned emotions. My mind was limp. After little investigation, it was concluded what had been suspected: Mr. Inman, my patient, had had a stroke. The intricate circuitry, the essence of individuality,

From the Department of Medicine, Duke University Medical Center, Durham 27710.

had been deprived of its obligate needs. The body cheated the mind. The diagnosis seemed to satisfy the family and attendings — I cried. All agreed it was time to proceed with the supportive care that temporarily would keep the patient alive. I felt abandoned. I realized I would never know Mr. Inman; I would never again talk with him.

Daily events soon deadened my memory of the episode. A melancholy comfort settled upon the family — even, I sensed, Mr. Inman. Our relationship had been demoted to various supervisory chores. Daily care became a ritual. Often, though, I would sit in his room and wonder. Why had this person affected me so profoundly? How had this patient caused me to cry? Perhaps it was the abruptness, the unexpected descent from vitality to this spiritless masquerade of life. Perhaps he heightened my fear of inadequacy, of making a mistake, of being wrong. If only his family had been less entrusting, less confident, maybe my guilt and unhappiness would have been less intense. Surely, it would have been easier to forget, easier to regard Mr. Inman as just another stroke victim. No, Mr. Inman reminded me how delicate life is; how merciless and objective the body can be. This patient exposed my own vulnerability and forced me to realize that medicine is all too often just intermittent intervention in the ensemble of body processes. Now, as I walk into his room and do the meager tasks to sustain him, I wonder: who is more helpless? who is more pitiful, Mr. Inman or me?

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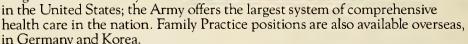
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While many clinical laboratories still report 250 mg/dL as "normal" cholesterol, the NIH Consensus Development Conference Statement on Cholesterol and Heart Disease<sup>3</sup> stated that any level above 220 mg/dL is associated with a significantly increased risk of coronary heart disease.

## You need to know, because high cholesterol parallels high blood pressure as a CHD risk factor.

Epidemiological studies and large-scale prevention trials have indicated that as with blood pressure, serum cholesterol levels are proportionately related to CHD risk.

Specifically, "...for every 10 mmHg rise in pressure, there appears to be about a 30% rise in cardiovascular risk." "...for every one percent you go up the American cholesterol scale, your subsequent rate of heart attack rises two to three percent." 5

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Antihypertensive therapy that does not increase cholesterol



See important information on following page.

References: 1. Glueck CJ: Ramarks in the symposium, Blood Pressure, Cholesterol and Coronary Heart Disease, Washington, D.C., March 31, 1985. 2. The Framingham Study, An epidemiological investigation of cardiovascular disease, Section 28, U.S. Dept. of Health, Education, and Welfare. 3. National Institutes of Health Consensus Development Confirence Statement, 1984; Vol.5, No.7, p.4. 4. Chobanian AV: The influence of hypertension and other hemodynamic factors in atherogenesis. Progress International Coronary Heart Diseases, XXVIIII, 1777, NovViDcc, 1983. 5. Castelli WP: Remarks in the symposium, Blood Pressure, Cholesterol and Coronary Heart Diseases, Washington, D.C. March 31, 1985. 6. Data on fila, Wyeth Laboratorias.

## **WyTensin** (guanabenz acetate)

#### Antihypertensive therapy that does not increase cholesterol

Before prescribing, consult the complete package circular.

Indications and Usage: Treatment of hypertension, alone or in combination with

Contraindication: Known sensitivity to the drug

Contraindication: Known sensitivity to the drug Precautions: 15 dealton Causes selation or drowsiness in a large fraction of pa-tients. When used with centrally active depressants: e.g. phenothizaties, barbin cates and benatoagepines, consider potential for additive sedative effects: 2. Parients with vascular insufficiency. Like other antihypertensives use with caution in severe contamy-insufficiency, rectimovacidal infaction, cerebrovacular dis-case, or severe hepatic or renal failure: 3. Rebound Sudden cessation of therapy with central abjust againsts it is "Verytain any rarely result in "overshoot" byper-tionium and more commonly produces increase in serum catecholamines and sub-iective symbolization.

INFORMATION FOR PATIENTS Advise patients on Wytensin to exercise caution when operating dangerous machinery of motor vehicles until it is determined they do not become drowsy or dizzy. Warn patients that tolerance for alcohol and other CNS depressants may be diminished. Advise patients not to discontinue therapy

acryptiv
LB TESTS In clinical trials, no clinically significant lab test abnormalities were
identified during acute or chrome therapy. Tests included CBC, urinalpsis, electroytests, SGCT, birthon, alkular phosphates are read oRb. creationing glacos, ceal
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DRUG INTERACTIONS Wytensin was not demonstrated to cause drug interactions when given with other drugs, e.g., digitalis, diureties, analgesies, ansiobytics, and autonfinamatory or antinified the agents, in clinical trials. However, potential for in creased sedation when given concomitantly with CNS depressants should be noted. DRUG/LAB TEST INTERACTIONS: No lab test abnormalities were identified with Wytensia use

Nytentia use

CARCINOCENESIS, MITAGENESIS, IMPAIRMENT OF FERTILITY. No evidence of cascinogene potential energed in rata during a two-pear coal study with Nytential nay top 9.5 mg, idea pt. e. Daut 10 miles maximum recommended human dose in the Salmonella microsome mutagenesity (Ames) pessessystem Wytenala at 200.5 mom genja in languperania practices eritated increases and one grap table or at 30.5 mg genja in supperania practices eritated increases and doses up to throw thick in one (TA 15.7) of for Salmonella inphimurium strains with or without inclusion of 21 later and cossession. No mutagenesi extripti was seen as a doses up to throw thick inhibit growth in the eularyone microorganisms. Notazonachim converge one of in Chinese humane converged to the control of the converged one of in Chinese humane descriptions. Wytenala produced no activity in an assay measuring induction of reparable DNA drauge Reproduced visualises showed decreased pregnancy rate paraspayers and one of 6 mg/kg/kg mas abouts been effected, assigned soft docereased pregnancy rate in a support of mates even though females received drug only during last third of pregnancy Calegory C. WYTENISM MAY MAY ALE ADDERSE EFFERENCY.

of mates even though femilies received drug only during last that of pregnancy PREGNANCY FEMILIA DEVELOPMENT AND THE METERS OF THE PRECNANCY FEMILIA DEVELOPMENT OF THE CONTROL OF THE CO

NURSING MOTHERS: Because no information is available on Wytensia excretion in human milk, it should not be given to nursing mothers

PEDIATRIC USE: Safety and effectiveness in children less than 12 years of age have not been demonstrated, use in this age group cannot be recommended.

Adverse Reactions: Incidence of adverse effects was assectationed from controlled clinical studies in U.S. and its based on data from 85 patients on Wytenata for up to Syzaars. There is some evidence that sude effects and cope effected following table shows incidence of adverse effects in at least 5% of patients in study comparing Wytenatia to placebo, at starting does of 8 mg b d. 1.

Adverse Effect	Placebo (%) n = 102	#ytensin (%) n = 109
Dry mouth	7	28
Drowsiness or sedation	12	39
Dizziness	7	17
Weakness	7	10
Headache	6	5

Heddache

In other controlled clinical trails at starting dote of 16 mg/day in 15 patients, in cidence of dry mouth was slightly higher (1888), and duziness was slightly heard (1283), but incidence of dry mouth was slightly heard adverse flexes as similar to placebo-con trolled trail. Although these side effects were not serious, they led to discontinuation of treatment about 15% of the time in more recent suited sessing annihal dose of 8 mg/day in 274 patients, incidence of drowniers on sedation was lower about 20%. Other adverse effects reported during clinical trails but not clearly distuit guistlable from placebo-effects and occurring with frequency of 3% or less Caraginative of the starting of the starting and the starting

Drug Abust and Dependence: No dependence or abuse has been reported Overdosage. Accordantaling-stone-acid hypotension, amonotence, lethage, letti-ability, missis, and bradycarda in two children gaed one and three years. Gastri-sages and person substance, flouds, and oral activated charcoal resisted of non-plete and uneventful recovery within 12 hours in both. Since experience with ac-cordantal overdosage is binned, suggested treatment its many supportive while drug us being eliminated and usual patient is no longer symptomatic. Yiell signs and fluid abinece aboud be carefully monitored Acquatar arrawy should be maintained and, if indicated, assisted respiration instituted. No data are available on Wytensia day, publish. Drug Abuse and Dependence: No dependence or abuse has been reported

Dosage and Administration: Individualize dosage: A starting dose of 4 mg b i d is recommended, whether used alone on with a this acide diuretic. Dosage may be increased in increments of 4 to 8 mg/day revery one to two weeks, depending on response. Maximum dose studied has been 32 mg b i d, but doses this high are

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  - 2.I'm type Z negative.
  - 3.I'm on the grapefruit diet.
  - 4.I gave six months ago.
  - 5. I just got back from Monaco.
  - **6.** The lines are thirteen blocks long.
  - 7. My mother won't let me.
  - **8.**I didn't sign up.
  - 9.I'm going out of town.
  - 10. Asthma runs in my family.
  - 11.I forgot to eat this morning.



Each one's a doozy, but we're hoping you won't use any of them. Give blood through the American Red Cross. Please, don't chicken out.

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## On-Call: Now, and Then

Robert J. Sullivan, M.D.

IT is 7:00 a.m. Monday morning. The long weekend oncall for our medical group is over again. I thumb through the multi-copy telephone pad I now use to document my calls and tear off copies of notes I will distribute to my colleagues informing them of who I saw and what I did on their behalf. As I sort the notes into small piles, I review them to see who would benefit from a follow-up call. Suddenly it strikes me how different my on-call experience is now when compared with that of a few short years ago.

The multi-copy pad is an innovation itself. I turned to this means of noting my calls after reading of medical-legal problems encountered by physicians relating to telephone consultations. As an expert witness, I reviewed a case where the defense was bolstered immeasurably by well-kept telephone notations which clearly refuted the plaintiff's claims of dereliction of duty. In the past, I always made note of any important problems I dealt with by telephone in a patient's record. Now I record every call regardless of importance. The log book adds little or nothing to the quality of patient care I render and clearly is a defensive response to the legal environment. It does provide some interesting retrospective interpretations as I look back through the pages.

In the past, when fee-for-service, private insurance payments or Medicare/Medicaid payments were the exclusive reimbursement systems in our area, the patient was invariably able to state the name of the physician in our medical group giving long-term care. Likewise, my colleagues could usually recognize the patient's name when I told them about the call the next day. In the past year, the arrival of several pre-payment programs led many people to designate our group as their "physician." They don't have anyone they know personally within the medical group. It is common to document calls from individuals who have never seen our clinic at all. Our medical director receives all my telephone notes with no designated physician. She will follow-up on needed treatments and arrange for a specific physician to manage ongoing problems.

Further review of the telephone pad shows the callers presenting a different pattern of complaints. In the past, the calls reflected a more urgent type of illness. Patients new to our medical group could be expected to call once or twice to assure themselves we were indeed available, or to gain needed information on self-management of medical problems. Then, we never heard from them except when a real need arose. I have heard this referred to as

"training your patient population." I prefer to think of it as a manifestation of mutual concern: they knew we were there if needed. With a regard for our need for rest they would avoid calling unless they felt we would really want to know what was transpiring. Recent telephone entrys reflect a different trend. Many callers are receiving prepayment services through their corporation. They represent a mobile, active and youthful group we did not see often in the past. They call at all hours for relatively trivial items. They want medical services rendered at night and on holidays at their convenience (". . . so I don't have to miss work. . . " is a typical comment). The tone is demanding with the implication of entitlement due to enrollment in "The Plan." Presumably, they envision a physician waiting for their call rather like the twenty-four hour telephone operator on the order desk of a catalogue store. Indeed, having never visited our facility and with no ongoing physician relationship, why should they think otherwise?

I also get calls from the emergency room that I never used to have. The hospital staff want me to come and evaluate someone who has just arrived unannounced and is on "The Plan." By telephone, I can sometimes manage the problem without a visit. Otherwise, I am obligated to trudge to the emergency room myself to ascertain illness severity. As we all know, the majority of the time such problems are not urgent and after evaluation the patient can safely be sent home for later follow-up in the office. In the past, I never knew of the visit until I received a copy of the emergency room report in my hospital box. My colleagues covering the emergency room would review the situation and call me only if a serious medical problem existed. Our administrator tells me we cannot economically permit emergency room visits for patients enrolled in the pre-paid plan. My patients don't always know what is and isn't a true emergency, and occasionally come to the hospital late at night seeking care. They need to be evaluated by someone. So now I see much more of the nurses on the night shift than I used to.

Clearly we are in a state of change. I feel there is a depersonalization of community practice in our area over the last decade. I am less a partner in a mutual effort of health promotion and illness management, and more of a repairman. Drop-in clinics, pre-paid medical plans and for-profit hospital expansion are the manifestations of an "industrialization" of our medical economy. Our United States system is unique in the world; and so expensive that I can see change is inevitable. I am sure my colleagues in California, Minnesota and other places have long since become acclimated to events that only now are sweeping into our area. I knew it was coming. I feel uneasy about where it is going!

From the Department of Medicine, Duke University Medical Center, Durham 22710.

I will take my stack of telephone notes to work and pass them along to the appropriate colleagues. They will riffle through them, perhaps call one or two of the patients, and then file the notes in the record. Our medical director will look at all the notes which I have designated "Dr. Clinic." I will put my telephone note pad away for a few days, glad for the respite from what is increasingly an unpleasant side of work: being on-call.

## Utilization Screens for Medicare Part B Carriers

The Health Care Financing Administration has instructed all Medicare Part B carriers to implement specific utilization screens. Listed below are the narrative descriptions, the procedure codes, and the parameters for the mandated utilization screens. Claims with services which exceed the stated parameters should contain documentation

to substantiate the *medical necessity* of services rendered. The prevailing rule for all Medicare claims is that only services which are *medically necessary* are eligible for reimbursement. Claims will be processed based on the medical necessity documentation submitted with the claims.

Service	HCPCS Code	Parameter	Service	HCPCS Code	Parameter
Joint injections	20600-20610	Three injections per month	Comprehensive office visits	90080	One service in six months
Mycotic nail debridements	11700-11711	One treatment per foot every 60 days	Skilled nursing facility visits	90340-90370	Two visits during the first week of
Nursing home visits	90430-90470, M0040 (Brief examination, two or more patients	One service per month			confinement and one per week thereafter
	seen in same nursing home, boarding home, domiciliary, or custodial care medical services) M0045 (Not		Injections	J Series	Twenty-four injections per year (excluding allergy, B-12, joint, and chemotherapy)
	otherwise classified, nursing home)		Assistants at cataract surgery	66820-66985 with modifier 80	All services will be reviewed for medical necessity
B-12 injections	J3420~	One injection per month	Concurrent Care	90240-90260 90640-90643	Inpatient care provided by
New patient office visits	90020	One per provider in three years		90292	different practitioners of same or similar
Holter monitoring	93270-93277	One service in six months			specialties on the same date

#### I'd Pick More Daisies

If I had my life to live over,

I'd try to make more mistakes next time.

I would relax. I would limber up.

I would be sillier than I have been on this trip.

I know of very few things I would take seriously.

I would be crazier. I would be less hygenic.

I would take more chances. I would take more trips.

I would climb more mountains, swim more rivers, and watch more sunsets.

I would burn more gasoline.

I would eat more ice cream and less beans.

I would have more actual troubles and fewer imaginary ones.

You see, I am one of those people who lives prophylactically and sensibly and sanely, hour after hour, day by day.

Oh, I have had my moments

And, if I had it to do over again, I'd have more of them.

In fact, I'd try to have nothing else. Just moments, one after another.

Instead of living so many years ahead of each day.

I have been one of those people who never go anywhere without a thermometer, a hot water bottle, a gargle, a raincoat, and a parachute.

If I had it to do over again, I would go places and do things.

And travel lighter than I have.

If I had my life to live over, I would start barefooted earlier in the spring.

And stay that way later in the fall.

I would play hooky more.

I wouldn't make such good grades except by accident.

I would ride merry-go-rounds.

I'd pick more daisies.

by Ray Lucht (85 years old at the time)

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## Modern Cardiologists Comment on Osler

 The editor recently came upon the following account published by William Osler in 1896 in the New York Medical Journal. Five modern cardiologists were asked to speculate on what had happened.

## Retention of Consciousness After Apparent Cessation of Heart's Action

can no longer be felt. Dr. Macrae, of Council Bluffs, has sent me notes of the following remarkable instance of the kind. A physician who had been the subject of angina, while waiting for Dr. Macrae in his reception room, was unconscious, with his head dropped over the back of the chair. He was pulseless; no cardiac sound could be heard. He regained consciousness and, with my assistance walked into the other room and lay upon the lounge. Careful examination again failed to reveal any cardiac movements.

He was not in pain, was sensible, but seemingly dazed. He asked me whether his heart had ceased action, I told him it had. He gave a short loving message to his wife, ejaculated, 'Lord have mercy on me!' became unconscious, and died then in a few seconds. He must have lived at least five minutes after I found him. When laid on the lounge he burst into a most profuse perspiration, and breathing was somewhat labored. The point I wish to make is that he lived, was rational, could almost walk by himself, and talked for several minutes after his heart, so far as could be determined, had ceased to beat.' In Case XXIII I was very much impressed by this retention of complete consciousness and capability of engaging in conversation when the pulse at the wrist could not be felt.''

## Joseph C. Greenfield, Jr., M.D., Department of Medicine, Duke University

In reviewing the description of the retention of consciousness after apparent cessation of heart action, I have elected to approach the answer as both a cardiologist and a detective. Obviously, the first axiom is that a patient will lose consciousness in approximately eight to ten seconds after cerebral perfusion stops. Thus, one must assume that cardiac function was maintained at least during a portion of this experience. The second assumption is that the patient did not have problems such as obesity, chronic lung disease, etc., so that Dr. Macrae was able to hear cardiac sounds if they occurred. (I am also assuming that Dr. Macrae knew how to use a stethoscope; was not deaf.)

The most likely diagnosis is that the patient had a malignant ventricular dysrhythmia similar to "Torsade de Pointes." When Dr. Macrae first entered the room and found the patient unconscious, the rhythm was a very rapid ventricular flutter in which no effective cardiac contraction occurred and thus the person had no cardiac sounds and was pulseless. A more ordered ventricular activation then occurred with the return of cardiac contraction allowing the patient to regain consciousness and walk to the next room. What followed next is the major difficulty. Dr. Macrae states examination at that time "failed to reveal cardiac movements." If the examination was detailed at this point and the heart was listened to for 10 to 20 seconds

then the description by Dr. Macrae is unlikely. However, if the examination was brief, the patient could have had another transient episode of disordered ventricular rhythm, i.e., lasting for only a few seconds followed again by more ordered cardiac action allowing him to make his final statement. Then ventricular fibrillation ensued and the patient died. The key to the above is how carefully and for what length of time Dr. Macrae examined the patient during the period he was conscious.

A second but less attractive alternative is that the patient was suffering from Stokes-Adams attack secondary to a markedly decreased but variable heart rate. Initially, the patient was unconscious with a heart rate less than six beats per minute and Dr. Macrae examined him during a ten to fifteen second period when asystole was present. The heart rate increased allowing the patient to walk to the next room and then another period of asystole occurred during Dr. Macrae's second examination. Again the key is the length of Dr. Macrae's examination.

The other possibility is that the patient was suffering from a massive myocardial infarction with a markedly reduced cardiac output. In this situation cardiac contraction may occur but the sounds are muffled and perhaps in this case inaudible. The fact that the patient was not experiencing pain and was conscious while sitting up would make cardiogenic shock a much less likely diagnosis. There may well be other explanations of the incident but I believe they would be in the realm of the supernatural.

#### Henry S. Miller, Jr., M.D., Department of Medicine, Bowman Gray School of Medicine

This is a fascinating report, and I have approached it from the standpoint of what has happened to me when people seem to survive for periods of time and finally die with various events.

There are several possibilities that I would think of in this situation.

Being a man with supposed coronary insufficiency as evidenced by angina, he perhaps could have had a rapid ventricular or supraventricular tachycardia causing a sudden hypotensive bout. Since he apparently was in the sitting position at the time and did not fall over, this would make him unconscious. The individuals with the rapid 180-220 heart rates frequently stabilize a bit before they have anything else happen. Perhaps with this stabilization, he could walk and converse with the physician. One should be able to feel some pulse at that time, but certainly if the rate exceeded the 220 mark it may not have been obvious in either the neck, wrist, or other areas. The heart tones in the older population I have listened to with this type problem were almost undetectable certainly in a waiting room type setting. It then probably resulted in ventricular fibrillation, resulting in his loving message to his wife and his demise.

Another experience that I have had in which hypotension would have caused unconsciousness, certainly in the sitting position, but in which a patient seems to remain conscious for about five minutes, is the case of sudden occlusion of the left main coronary artery. The two times it has happened to me have been in the catheterization laboratory. The patient would seem to maintain an electrocardiographic pattern that, on these two occasions, was a sinus tachycardia but would have pressures only detectable through the arterial line, not recorded by a cuff, and in which the heart was not recognizably beating when examined by stethoscope. In spite of the usual resuscitative efforts including intubation, closed chest massage, medications, etc., both of these patients continued to have a gradual increase in heart rate, gradual drop in recognizable blood pressure to a ventricular fibrillation and died. Perhaps in the setting of a waiting room this same type of event occurred. Both of these men were able to talk to us at least through a portion of this five minute interval.

The other possibility would perhaps be a sudden dissecting aneurysm of the ascending aorta with pericardial tamponade, occlusion of upper extremity pulses. These people at times get initially hypotensive, begin to stabilize a bit with improvement in consciousness and the blood pressure stabilizes. This combination may make it impossible to hear heart sounds, feel pulses, and gradually result in the sequence of death as described.

This is certainly an interesting phenomenon. It is always fascinating to be present when somebody develops a fatal arrhythmia, be able to do closed chest massage, keep them coughing for awhile and conversing with you until nothing can be maintained any longer. Under other circumstances, this could certainly have been carried out by Dr. Macrae probably with this individual also.

## Galen S. Wagner, M.D., Department of Medicine, Duke University

The patient was most likely in cardiogenic shock. Since not all parts of the body are necessarily in equal degrees of shock, one part may still have sufficient flow to function when others do not. In shock, the pulse pressure may be so narrow that a pulse is not perceived. Stroke volume may be so low that heart sounds are not easily appreciated. I have observed this phenomenon on several occasions in patients in the CCU with a Swan-Ganz catheter in place. The cardiac index will be extremely low, the arteriovenous oxygen difference will be very wide. The left ventricular filling pressure will be high, although the patient will not be clinically in pulmonary edema. The skin will usually be cool and clammy and the urine output will be very low.

This "unequal manifestation of shock" occurs most commonly soon after the onset of shock. I would guess that if a Swan-Ganz catheter had been in place in the patient in Dr. Macrae's reception room, the findings would have been very similar to those we observed on the CCU.

It is interesting to note that the high peripheral resistance which minimizes the pulse pressure and, thereby, accounts for one of the most unusual features of this phenomenon is also responsible for further diminishing the stroke volume. A treatment, therefore, would be intravenous sodium nitroprusside. By decreasing peripheral resistance and, thereby, left ventricular afterload, there might be an increase in the stroke volume and reversal of the cardiogenic shock.

## Andrew G. Wallace, M.D., Office of the Chief Executive Officer, Duke University Hospital

This patient was an adult male, who presented to his physicians because of pain in the chest of uncertain duration. While waiting to be seen he became unconscious and no pulse or heart sounds could be detected. He regained consciousness and could walk with assistance and talk, while still apparently pulseless and having no audible heart sounds. About five minutes later he ejaculated, lost consciousness again and died.

A sudden fatal event preceded by chest pain raises the question of acute myocardial infarction, pulmonary embolus or aortic dissection. Absent pulses at the wrist after the patient regained consciousness and could walk suggests aortic dissection. It would be unusual not to hear heart sounds in a patient who is conscious in the upright position, especially with acute MI or pulmonary embolus, but might well occur with pericardial tamponade from aortic dissection. Ejaculation is a consequence of combined autonomic nerve discharge (principally sympathetic), can be produced by lumbar sympathetic nerve stimulation and again is most compatible with aortic dissection.

My impression is that Dr. Macrae's patient died from a dissecting aortic aneurysm with rupture into the pericardial sac.

## Andrew S. Wechsler, M.D., Department of Surgery, Duke University

My notion is that the patient had a rhythm disturbance, perhaps related to a happening myocardial infarction or ischemic event. I suspect this was ventricular tachycardia/fibrillation without adequate conduction of a peripheral pulse. Presumably he had some forward output but not enough to generate a blood pressure that could be palpated because of the narrowness of the pulse. This terminated in ventricular fibrillation.

## Alan Woelfel, M.D., Department of Medicine, The University of North Carolina at Chapel Hill

I think that the word "apparent" in Osler's title is important, for I believe that had an electrocardiogram been available at the time, it would have shown sustained ventricular tachycardia (VT), subsequently deteriorating into ventricular fibrillation and causing the patient's death. The patient had the most common predisposition to VT, coronary artery disease; his clinical features are also consistent

with what I have frequently witnessed as a clinical electrophysiologist in patients with episodes of spontaneous (or intentionally induced), sustained VT. The original syncope can be explained by low blood pressure associated with the VT, which increased sufficiently to restore consciousness when the patient was placed in the supine position, but remained too low to generate a palpable pulse. Diaphoresis frequently accompanies VT as the sympathetic nervous system attempts to compensate for hypotension, and dyspnea results from the high filling pressures associated with the tachycardia. Although I have not listened to the precordium under these catastrophic circumstances it is reasonable to speculate that myocardial contractions too weak to generate a palpable pulse could also be too weak to be audible. Ventricular tachycardia rapid enough to cause this clinical picture frequently degenerates into ventricular fibrillation, as it likely did in this case. Dr. Macrae fortuitously witnessed what has now been confirmed by Holter monitors that have serendipitously been in place when patients have died suddenly: ventricular fibrillation is frequently preceded by a period of sustained ventricular tachycardia.

The editor and our readers appreciate the thoughtful comments of the cardiologists. The practice of medicine remains a challenge to all of us, even William Osler.

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### Letters to the Editor

#### Medical Review of NC - Part II

#### To the Editor:

I would like to second the words of Dr. James A. Bryan's Letter to the Editor in the February 1986 North Carolina Medical Journal (1986;47:97).

Our hospitals and doctors spend an excessively large amount of time, which they don't really have, with these reviews.

I doubt seriously if there is either savings, improvement in medical care, or other usefulness of this organization.

Clarence M. McMurray, M.D. 808 Schenck Street Shelby 28150

#### To the Editor:

I am greatful to Dr. Alexander for his comments (NCMJ 1986;47:225). One of the major problems is that the MRNC has "run amuck" in its relationships with the practitioners. It does not seem to be under the control or influence of the N. C. Medical Society, and the "input" by practitioners is marginal at best. The greater problem of implementing society's choices between battleships and health care is being obfuscated and I am afraid that my professional colleagues are being used as a smokescreen between the public and its choices.

James A. Bryan II, M.D. UNC School of Medicine Chapel Hill 27514

#### Norris Biggs Big Anniversary

#### To the Editor:

Thank you very much for your advice a few months ago in looking into the history of specialty clinics and continuation of established hospitals. After four months of blind alleys through the archives and libraries, I can find no precedent for an organization such as the Norris-

Biggs Clinic and the Rutherford Hospital. Evidently, this is a continuous relationship that has extended 75 years, as of this year, without interruption.

We are hoping to recognize the uniqueness of the Norris-Biggs Clinic and the Rutherford Hospital this spring. Before that time, we would like to be sure, in spite of the paucity of records available, that we are establishing a genuine priority. By this letter, I am asking anybody in the North Carolina Medical Society for information indicating that indeed we are not the oldest combined specialty clinic and hospital in continuous operation at the same location.

> Austin T. Hyde, Jr., M.D. Norris Biggs Clinic Box 970 Rutherfordton 28139

#### Beard Bibliography

#### To the Editor:

For some reason the bibliography from my article about Joe Beard failed to appear in the article in January's *North Carolina Medical Journal* (NCMJ 1986;47:37-8). Here they are.

- Beard JW, Finkelstein H, Sealy WC, Wyckoff RWG. Ultracentrifugal concentration of the immunizing principle from tissue diseased with equine encephalomyelitis. Science 1938;87:89.
- Beard JW, Finkelstein H, Sealy WC, Wyckoff RWG. Immunization against equine encephalomyelitis with chick embryo vaccines. Science 1938;87:490.
- Fothergill LD, Dingle JH, Farber S, Connerly ML. Human encephalitis caused by the virus of Eastern variety of equine encephalomyelitis. New Engl J Med 1938;219:411.
- Wesselhoeft CC, Smith EC, Branch CI. Human encephalitis: four fatal cases due to virus of enquine encephalomyelitis. JAMA 1938;111:1735.
- Howitt BF. Recovery of the virus of enquine encephalomyelitis from the brain of a child. Science 1938;88;455.
- Holden M, Wyckoff RWG. Western equine encephalomyelitis in a laboratory worker. JAMA 1939;113:206-7.

Will C. Sealy, M.D. P.O Box 6000 Macon, GA 31208

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> Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

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types of sausages smoked by traditional methods should be eaten in moderation.

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#### IN STATE

#### May 16-17

Annual Autism Conference

Place: Chapel Hill

Credit: 10 hours Category I AMA

Fee: \$100

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill

27514. 919/962-2118

#### May 17

Info:

Neoplastic Hematopathology Conference

Place: Greenville

Credit: 6 hours Category I AMA

Fee: \$55

Info: Office of CME, ECU, Box 7224, Greenville 27835-7224, 919/

758-5200, ext. 2108

#### May 20-23

NC Health Promotion and Wellness Institute

Raleigh

Credit: 19 hours Category I AMA; 19.5 hours AAFP

Jacqueline Rollins, Wake AHEC, 3000 New Bern Avenue, Info: Raleigh 27610. 919/755-8018

#### May 21

Polypharmacy/Drug Interactions

Place: Sanford

Info: Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

#### May 23-24

Pediatric Infectious Diseases of the Lung and Gut

Place: Durham

Credit: 10 hours Category I AMA

Fee: \$90

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-Info:

ham 27710. 919/684-6878

#### May 28-30

Sea Level Invitational Conference on Geriatric Medicine

Place: Sea Level

Info: Office of CME, ECU, Box 7224. Greenville 27835-7224. 919/ 758-5200, ext. 208

#### May 29

What's New in the Treatment of Cardiovascular Disease

Place: Durham

Credit: 6 hours Category I AMA

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### June 3

Duke Tuesday Place: Durham

5 hours Category I AMA Credit:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-Info: ham 27710. 919/684-6878

#### June 6-7

Cardiology Scientific Session and Alumni Reunion

Place:

Chapel Hill W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118

#### June 7

Short Course in Diagnostic Imaging: Body II

Place:

Credit: 8 hours Category I AMA

info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### June 8-13

Fellowships in Family Medicine

Place: Chapel Hill

Credit: 100 hours Category I AMA Info:

W. B. Wood, M.D., 231 MacNider 202H, UNC, Chapel Hill 27514. 919/962-2118

#### June 12-14

33rd Annual Mountaintop Medical Assembly

Place: Waynesville

Info: Debbie Ford, 37 Miami Drive, Waynesville 28786. 704/452-

#### June 18

What's New and Old in Gl Disease

Place: Sanford Info:

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518

#### June 19-21

Seaboard Medical Association of North Carolina and Virginia Annual Session

Place:

Kill Devil Hills Info:

Julian R. Taylor, M.D., Box 10387, Raleigh 27605. 919/821-

#### June 21

Diabetic Retinopathy and the Dye Laser Place:

Raleigh Info:

Southern Eye Associates, 3320 Executive Drive, Raleigh 27609.

#### June 27-28

Contact Lenses and Refractive Surgery: What Is the Balance? Place:

Wrightsville Beach Info:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### July 4-6

Sports Medicine Symposium

Place: Wrightsville Beach

Fee: \$30

Info: Alan Skipper, NCMS, Box 27167, Raleigh 27611. 919/833-3836

#### July 7-11

28th Annual Postgraduate Course/Morehead Symposium

Place:

Credit:

Atlantic Beach 26 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878 Info:

#### July 9-22

Reconstructive and Cosmetic Surgery

Durham Place:

Credit: 25 hours Category I AMA

Linda Mace, Box 3707 DUMC, Durham 27710. 919/684-8111

#### July 16

Cost of Medical Care

Sanford Place:

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518 Info:

#### July 28-August 1

9th Annual Radiology Postgraduate Course

Place:

Atlantic Beach
Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-Info:

ham 27710. 919/684-6878

#### OUT OF STATE

#### May 15-18

Annual Meeting, The Virginia Society of Otolaryngology-HNS Place: Wintergreen, VA

Donna Strawderman, 4205 Dover Road, Richmond, VA 23221. Info:

804/353-2721

#### May 21-24

Eighth Annual Evoked Potential Symposium

Place: Hilton Head Island, SC

Credit:

30 hours Category 1 AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878 Info:

#### May 29-June 1

Annual Meeting, The Virginia Society of Ophthalmology Place: Norfolk, VA

Place:

Donna Strawderman, 4205 Dover Road, Richmond, VA 23221.

804/353-2721

#### June 11-14

Dermatology for Non-Dermatologists

Place: Myrtle Beach, SC

Credit: 15.5 hours Category I AMA

Fee: \$350

Info: Division of Dermatology, Box 3135 DUMC, Durham 27710.

919/684-2504

#### June 19-22

Annual Duke Conference: Contemporary Developments in Anesthesiol-

ogy Place: Hilton Head Island, SC

Credit:

17 hours Category 1 AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-Info:

ham 27710. 919/684-6878

#### June 24-29

Second Annual Advances in Internal Medicine

Place: Hilton Head Island, SC Credit:

16 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878 Info:

#### June 30-July 5

Midsummer Family Practice Digest

Place: Myrtle Beach, SC

Credit: 30 hours AAFP

Mary Anna Hendley, NC Academy of Family Physicians, Box 20146, Raleigh 27619. 919/781-6467 Info:

#### July 16-20

Seminar on Preventive Medicine: Nutrition

Place: Hilton Head Island, SC

Credit: 12 hours Category I AMA

Info: Harold D. Schutte, 53 S. French Broad, Asheville 28801. 704/

258-0969

#### July 29-30

Advanced Neurosonology Seminar

Place: Snowmass, CO

Info: Frederick Kremkau, M.D., Bowman Gray School of Medicine,

Winston-Salem 27103. 919/748-4505

#### July 31-August 2

Advanced Applied Ultrasound in Obstetrics

Snowmass, CO Place:

Frederick Kremkau, M.D., Bowman Gray School of Medicine, Info:

Winston-Salem 27103. 919/748-4505

#### September 11-13

Doppler Echocardiography Seminar Place: Tarpon Springs, FL Credit: 14 hours Category I AMA

\$350 Fee:

Frederick Kremkau, M.D., Bowman Gray School of Medicine, Winston-Salem 27103. 919/748-4505 Info:

#### October 17

Selected Topics in Pediatrics

Place:

Norfolk, VA Jean E. Shelton, M.D., 800 West Olney Road, Norfolk, VA Info:

23507. 804/628-7179

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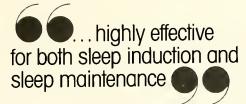
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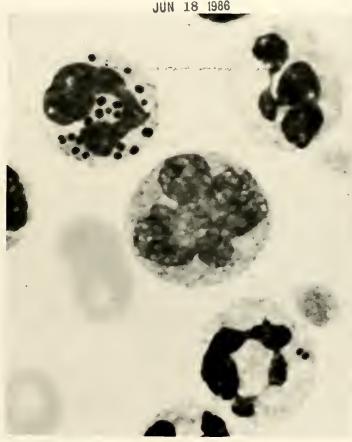
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### Bugs in the Blood: Acute Staphylococcal Septicemia and Endocarditis Diagnosed by Staining the Buffy Coat

David C. Whitcomb, Ph.D., M.D.

THE value of blood cultures in confirming septicemia is undisputed. Most doctors do not realize the similar value of a buffy coat Gram's or Wright's stain and so they are rarely utilized in current medical practice. I recently saw a patient with a complex and confusing presentation in whom this test was diagnostic of septicemia and suggested, in concert with clinical findings, the diagnosis of acute staphylococcal endocarditis.

The patient was a 28-year-old construction worker who came to the emergency room with spiking fevers and disorientation. He had no history of previous illnesses, exposure to toxins or contagious diseases. He denied homosexual contact, drug or tobacco use but stated that he occasionally drank beer on weekends.

Two weeks earlier he noted generalized weakness which worsened daily. One week before admission he began having shaking chills, fever, nausea, vomiting and a cough that produced blood-tinged white sputum. He developed severe back pain, hematuria and acholic stools. Finally, his girl friend noted scleral icterus and periodic confusion and brought him to the emergency room.

His temperature was 40.2° C; pulse rate, 120-150; and respiratory rate, 52. His sclera were markedly icteric. Breath sounds were diffusely diminished with scattered rhonchi and basilar crackles. There were no cardiac murmurs. The liver was mildly tender and measured 16 cm by percussion in the right mid-clavicular line. No lymphadenopathy was noted.

The white blood cell count was 24,000/mm<sup>3</sup> with 62% neutrophils, 20% immature neutrophils and there was 12.4 g/dl of hemoglobin. The sodium was 116 mEq/l (normal 135-145); chloride, 83 mEq/l (normal 100-106); bicarbonate, 19; urea nitrogen, 77 mg/I00 ml (normal 8-25); and creatinine, 2.8 mg/100 ml (normal 0.7-1.5). On urinalysis there were 10-20 white blood cells and 2-4 red blood cells per high power field as well as many hyaline and coarse granular casts. A chest roentgenogram showed diffuse bilateral patchy alveolar infiltrates.

Because of the high spiking temperature, elevated white blood cell count and chest roentgenogram, we suspected septicemia. Blood cultures were obtained and an additional EDTA ("purple top") tube was drawn for buffy coat stains.

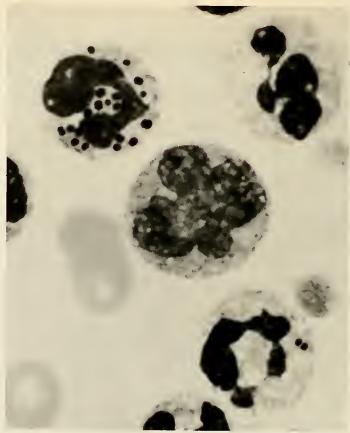
Numerous plump, intracellular, gram-positive organisms were seen on the buffy coat Gram's and Wright's stain (figure 1) and a diagnosis of gram-positive septicemia was made. This led to a more thorough search for embolic phenomena. Funduscopic exams showed three Roth's spots (small retinal hemorrhages with pale central areas). One Janeway lesion (nonpainful, palpable, purpuric lesion several millimeters in diameter, most often seen on the palms) was seen at the proximal end of the left index finger. Nafcillin was immediately started. A subsequent echocardiogram showed a large vegetative lesion on the tricuspid valve. After repeated questioning the patient admitted having used intravenous drugs several weeks previously, and the diagnosis of acute staphylococcal endocarditis secondary to intravenous drug abuse became clear.

The patient was admitted to the intensive care unit where rifampin was added to the antibiotic regimen. Blood cultures grew two strains of staphylococcus aureus from each of the blood culture tubes. On the day after admission he developed adult respiratory distress syndrome and mechanical ventilation was required. His condition stabilized but he subsequently developed an antibiotic-resistant Citrobacter freundii pneumonia and septicemia. Vascular collapse, profound hypotension and anoxic brain injury ensued despite rigorous therapy, and he succumbed to his illness on the thirteenth hospital day.

This experience illustrates the utility of the buffy coat smear in rapidly identifying the source of an extremely severe, complex and potentially treatable illness. Use of the buffy coat smear in modern medicine, although mentioned in several textbooks, is rare. Advantages include its speed, low cost (free if you do it yourself!) and specificity when intracellular organisms are seen. Of course, inability to identify organisms does not exclude serious

Although both Wright's and Gram's stains are useful, the buffy coat prepared with Gram's stain has advantages. With a Gram's stain both the red and white blood cells appear light pink. On a well prepared slide, the only blue structures seen are the gram-positive organisms. Because the white cells are highly concentrated in the buffy coat, it is possible to scan thousands of white cells in a short time. With a Wright's stain, gram-positive organisms also stain dark blue although the presence of similar colored intracellular structures slows the scanning process.

From the Department of Medicine, Duke University Medical Center, Durham 27710.



**Figure 1.** Wright's stain of the buffy coat. Note the numerous intracellular organisms within the polymorphonuclear neutrophils, and the presence of immature granulocytes.

Staphylococcus aureus, one of the most serious grampositive pathogens, may be seen more often than other gram-positive organisms on buffy coat stains. The reason is because some strains of staphylococcus survive for long periods of time in the polymorphonuclear leukocytes after being phagocytized, and as increasing numbers of leukocytes circulate with intracellular organisms the chance of them being observed increases. Indeed, prolonged survival of the staphylococcal organism within leukocytes may be the key to their virulence. Studies with human leukocytes have shown that the less virulent coagulasenegative staphylococcus was killed less than 20 minutes after ingestion whereas the more virulent coagulase-positive staphylococcus not only survived for more than 90 minutes, but continued to multiply within the leukocytes.1 Another study found a large fraction of phagocytized coagulase-positive staphylococcus survived for more than 24 hours.2 Therefore, as more serious staphylococcal infections persist, increasing numbers of leukocytes would be expected to have intracellular organisms and the chance of observing them on the buffy coat smear increases.

The intracellular residence of staphylococcus may improve the diagnostic sensitivity of the buffy coat stain but, as in the case of tubercule bacilli and brucella, intracellular residence also protects the organism from antibiotics such as penicillins, cephalosporins, aminoglycosides and vancomycin. <sup>2, 3</sup> Rifampin, an antituberculosis antibiotic that acts intracellularly, is a potent antistaphylococcal antibiotic and has been successfully used in treating persistent staphylococcal infections. <sup>3,5</sup>

Most gram-negative organisms are difficult to identify by buffy coat stains for several reasons. First, gram-negative organisms when Gram stained are the same color as the polymorphonuclear leukocytes, making rapid identification difficult. (With Wright's stain some gram-negative organisms, such as N. Gonorrhea, appear dark blue and are easily seen.) Second, unlike staphylococci, most gramnegative organisms do not have prolonged intracellular survival. In addition, relatively few gram-negative organisms need to be present in the blood to cause septic shock and death. One notable exception is Yersinia pestis (plague) sepsis. During the overwhelming infectious process these

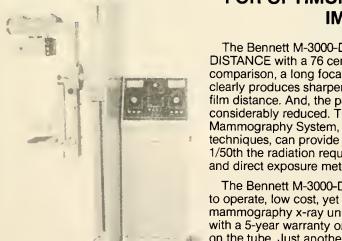
gram-negative bacilli are even seen on the unspun peripheral smear.6 So when you see a patient you suspect to have a serious infection, don't forget the buffy coat stain.

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#### Acknowledgment

I wish to thank David L. Simel, M.D., Mark Linzer, M.D., and Francis A. Neelon, M.D., for their assistance in preparing this paper.

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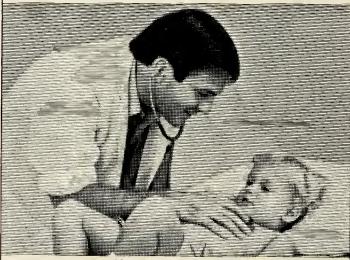
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At the same time, Wytensin lowered blood pressure as effectively as hydrochlorothiazide, propranolol, clonidine or methyldopa. Drowsiness and/or dry mouth, the most frequent side effects noted with Wytensin, usually diminish or disappear over time. In fact, in double-blind studies to date, discontinuance of therapy for all side effects occurred in about 13% of patients.



See important information on following page

References: 1 Glueck CJ: Remarks in the symposium, Blood Pressure, Cholesterol and Coronary Heart Disease, Washington, D.C., March 31, 1985. 2. The Framingham Study, An epidemiological investigation of cardiovascular disease, Section 28, U.S. Dept. of Health, Education, and Welfare. 3. Netional Institutes of Health Consensus Development Conference Statement, 1984: Vol 5, No 7, p. 4. 4. Chobanian AV: The influence of hypertension and other hemodynemic factors in atherogenesis. Progress In Cardiovascular Diseases, XXVI (3): 1777, Nov/Dec, 1983. 5. Cestelli WP: Remarks in the symposium, Blood Pressure, Cholesterol and Coronary Heart Disease, Weshington, D.C. March 31, 1985. 6. Data on file, Wyeth Laboratories.



#### Antihypertensive therapy that does not increase cholesterol

ing, consult the complete package circular.

Indications and Usage: Treatment of hypertension, alone or in combination with a thiazade distretion

a Gazando directee.

Contraindication: Known sensitivity to the drug

Precautions: I Sedation Causes sedation or drowniess in a large fraction of pa

Precautions: I Sedation Causes sedation or drowniess in a large fraction of pa

tests when used with centrally active depressants; e.g. phenothazines, barbin;

rates and bennodazepines, consider potential for additive sedative effects a 2.0

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INFORMATION FOR PATIENTS Advise patients on Wytensin to exercise caution when operating dangerous machinery or motor vehicles until it is determined they do not become drowsy or dury. Warn patients that olerance for alcobol and other CNS depressants may be diminished. Advise patients not to discontinue therapy

outputs.

Lab TESTS In clinical trails, no clinically significant lab test abnormalities were identified during acute or chronic therapy. Tests included CBC, unralysis, electro-less SGOT biotripos, halianie phosphatase une cast QBC, terationie, glocos, calcium, phosphorus, total protein, and Gombis test. During long-term use there was waitly decrease in exercise the control of t

DRUG INTERACTIONS Wytensin was not demonstrated to cause drug interactions when given with other drugs, e.g. digitals, discreties, analgesies, anxiolyties, and antishammatory or antisficieties agents, in cliental trials However, potential for increased sedation when given concomitantly with CNS depressants should be noted DRUG/LAB TEST INTERACTIONS No lab test abnormalities were identified with

Wytensio are

(ARCINOSEPSIS MUTAGENSIS, IMMARMINT OF FETTUITY Nov-adecise of carcinoger patronial energical rivariant during in two ear or also day with Wytensio artipute 9 to great patronial energical rivaria during in two ear or also day with Wytensio artipute 9 for great at 9 to 9 to great patronial energical rivaria during in the submorella microsome mutagenerity (Ames I sex system Wytensio at 200, 400 meg per piate or at 30 9 forneg min suppersona) gave does critical energesses in number of mutants in one (TA 1873) of the Salmonella hyphimarium strains with one great piate or at 30 9 forneg min supperson No mutageneric carcino yea see and does up to those tenha for a financial mutant of the machine or any cell and one great piate of the second or any cell produce up to those tenha for one year pombe, or in Chancels humine or vary cells and one up to those tenha for one year pombe, or in Chancels humine or vary cells and one up to those tenha produced no continued to the control of the contro of maties, even though females received drug only during last third of pregnancy of maties. WTHENIN MAY HAVE ADVERSE EFFECTS ON FETUS WHEN ADMINISTRATED TO PRECHANT WOMEN. A TERTOROGY study in mice indicated possible increase in shelteral abnormalizes when "Wytenatas is given orally at dones 3 to 6 times maximum recommended human dose of 10 mg kg at Three abnormalizes, principally costal and verterbat, were not oncret din sumilar studies in rate and rabbits flowester, increased fetal loss bas been observed after the contract of the properties of the mg kg and rabbits (20 mg kg) and patient (20 mg kg) and patient (20 mg kg) and patient (20 mg kg) and capted (20 mg kg) and ca

NURSING MOTHERS Because no information is available on Wytensin excretion in human milk it should not be given to nursing mothers PEDIATRIC USE Safety and effectiveness in children less than 12 years of age have not been demonstrated, use in this age group cannot be eccommended

Adverse Reactions: Incidence of adverse effects was ascertained from controlled clinical studies in US and as based on data from 89 patients on Wytensian for up to 39 years There is some evidence that side effects and cone related following table shows incidence of adverse effects in at least 5% of patients in study comparing Wytensia to placebook at starting does of 8 mg b d.

Adverse Effect	Placebo (%) n = 102	Wytensin (%) n = 109
Dry mouth	7	28
Drowsiness or		
sedation	12	39
Dizziness	7	17
Weakness	7	10
Headache	4	

Headache

In other controlled clinical trials at starting dose of 86 mg/dav in 156 patients, in others, controlled clinical trials at starting dose of 86 mg/dav in 156 patients, in odders of dry month was slightly hugher (1888) and distributes was slightly hugher (1888). In distributes was slightly hower (1889), but incloders of most frequent adverse efficies as sensitiated placeboson trolled trial. Although these side effects were not sensous they led to discontinuation of transternal board 18% of the time Innoversection stadies using an initial dose of 8 mg day in 2\*4 patients, incidence of drownesses or sedation was lower, about 68 mg day in 2\*4 patients, incidence of drownesses or sedation was lower, about 68 mg day in 2\*6 patients with the starting suitable from placebo effects and occurring with frequency of 3 for fees. Carrial of the starting suitable from placebo effects and occurring with frequency of 3 for fees. Carrial of the starting suitable from placebo effects and occurring with frequency of store that of the other starting suitable from placebo effects and occurring with frequency distorbance of seven Moscobiodical aches in extremities, muscle aches in Reputatory—dryspera Dermatologic—tash, purious Urogania and English and Starting Starting and Starting 
Drug A buse and Dependence: No dependence or a buse has been reported to verdousge: Accidental ingestion caused hypotension, sommolence letharge, it is ability, moissi, and brajecrafia in move oblitiers and one and three years. Gastire lavage and pressor substances, Buids, and oral activated charcosi resulted in complete and unevental recovery without 12 hours in both Since expenence with a cidental loverdousge is limited, suggested treatment is mainly supportive while drug is being eliminaried and usual pattern too longer symptomatic. Viril sugges and Buid balance should be carefully constored Adequate airway should be maintained and, if indicated, assisted respiration instituted. No data are available on Wytensin dishyability. Drug Abuse and Dependence: No dependence or abuse has been reported

Dosage and Administration: Individualize dosage: A starting dose of 4 mgh 1 d is recommended, whether used alone or with a bisarde discrete. Dosage may be increased in Increments of 4 to 8 mg/dr verery one to two weeks depending on terponse. Maximum dose studied has brein 32 mg b 1 d, but doses this high are startly needed.

How Supplied: (grazabenz acetate) Tablets, 4 mg, bottles of 100 and 500: 8 mg and 16 mg, bottles of 100

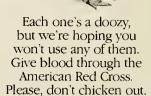


#### 6 1984, Wyeth Laboratories

#### **TWELVE IMPECCABLE EXCUSES FOR NOT GIVING** BLOOD.

- 441. I think I have lumbago.
  - **2.** I'm type Z negative.
  - 3.I'm on the grapefruit diet.
  - 4. I gave six months ago.
  - **5.**I just got back from Monaco.
  - **6.**The lines are thirteen blocks long.
  - 7. My mother won't let me.
  - **8.**I didn't sign up.
  - 9.I'm going out of town.
  - 10. Asthma runs in my family.
  - 11. I forgot to eat this morning.

**12.** I'm allergic to flowering magnolia.



**EXCUSES DON'T SAVE LIVES. BLOOD DOES.** 



#### SCIENTIFIC ARTICLE

### Changing Trends in Small Cell Lung Cancer

Don V. Jackson, Jr., M.D.

MALL cell lung cancer is a major health problem in our country. It accounted for approximately 20-30% of the estimated 126,000 deaths from lung cancer in the United States last year, 3,000 of them in North Carolina. The etiologic relationship with tobacco smoking has been firmly established. Unlike non-small cell lung cancer, it has a large growth fraction and has been found to be very responsive to radiotherapy, chemotherapy, or the combination of the two. Correspondingly, the median survival has increased from 6-17 weeks prior to the 1970s to about one year since then. Discussion of long-term survivorship and even "cure" has appeared in the literature. As a survival that the literature.

The cornerstone of therapy has been combination chemotherapy. The value of chest radiotherapy remains controversial. 4.5 In two recent randomized trials the survival outcome of patients with rather localized disease appears to be improved with the addition of thoracic irradiation to combination chemotherapy. 6.7 Although the short-term outlook for patients with either locally advanced or extensive small cell lung cancer has been greatly improved, survival curves do not show a "cure plateau." and better treatment methods are needed.

The current study is a review of the clinical trials conducted at the Bowman Gray School of Medicine and the Piedmont Oncology Association since 1974. It focuses on the changing trends observed in this disease and points out areas needing further clinical research.

#### Materials and Methods

Five trials involving a total of 562 patients have been conducted since 1974 at Bowman Gray School of Medicine and the Piedmont Oncology Association. 9-15 The trials have tested prophylactic cranial irradiation (Trial I), 9 immunotherapy (Trial II), 10 VP-16 (Trial III), 11-12 hemibody radiotherapy (Trial IV), 13-14 and cis-platinum (Trial V), 15- All patients have received chest radiotherapy consisting of 3,000 rad in 10 fractions with the exception of those in the last two trials. In Trial IV 600 rad upper hemibody was given in addition to 2,000 rad local chest radiotherapy. In the current Trial (V) only patients with localized disease ("limited disease") receive chest radiotherapy (4,800 rad given in a split course). Prophylactic cranial irradiation has been used routinely since Trial I in which there was a significant reduction of brain metastasis following 3,000

rads given in 10 fractions compared with controls who did not receive it.9 In the current trial prophylactic cranial irradiation is being used only in patients with localized disease and those with extensive disease who attain a complete response. In all of the trials, cyclophosphamide, doxorubicin, and vincristine (CAV) have been the nucleus of the combination chemotherapy program. In Trials I and II methotrexate and CCNU were also given. In Trial III, patients were randomized to receive VP-16 in addition to CAV. In the current study, VP-16 plus CAV is being given to all patients and cis-platinum is being administered in a randomized fashion.

The data from these trials have been analyzed with respect to extent of disease, which was established during the pretreatment evaluation. Limited disease refers to disease confined to one hemithorax including ipsilateral supraclavicular adenopathy. Extensive disease refers to all else including pleural effusion. Staging before treatment has included evaluation of the chest x-ray and bone marrow, hemogram, liver chemistries, and scans of the brain, liver and bone. Computerized tomography of the abdomen has been used routinely in the current trial. A complete response was defined as 100% reduction of all demonstrable tumor and no new areas of malignancy. Reevaluation with invasive procedures such as bronchoscopy, liver biopsy, and bone marrow examination was not mandatory. A partial response was at least a 50% reduction of the product of the longest perpendicular diameters of the indicator lesion(s) since first measured and no new areas of malignancy.

#### Results

Patient characteristics are given in table 1. Of the 562 patients entered into these five clinical trials, 478 (85%) were evaluable for analysis. The median age has been from 58 to 63 years (range 28-79 years). The male gender has predominated, accounting for approximately 70% of the patients. Perhaps a slight increase in the number of women has occurred more recently as observed in Trial III in which 36% of the patients were women. For a 5-year period between 1974 and 1979 (Trials I and II) extensive disease was present at diagnosis in two-thirds of the patients. During the next 5 years (Trials III and IV) the extent of disease was almost equally divided between limited and extensive disease. Currently a greater percentage of patients have been found to have extensive disease (tables 1 and 2) but the number of patients in this study is small. The performance status at the onset of study appears to have remained fairly constant through the years; Trial I contained

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Supported in part by NIH Grants CA-12197 and CA-33499, National Cancer Institute, Bethesda, MD.

Table 1
Patient Characteristics

Trial	Evaluable patients	Median age (Range)	Male sex	Extensive disease	Performance status (0-2)†
1	54*	59 (43-77)	72%	65%	94%
11	102	58 (36-78)	70%	65%	95%
III	242	58 (28-78)	64%	47%	95%
ΙV	46	63 (40-79)	72%	48%	98%
V	34	59 (41-75)	76%	82%	100%

\* Included 8 patients who presented with brain metastasis

Table 2
Pretreatment Sites of Involvement\*

Trial	Nodes	Bone	Liver	Pleural Effusion	Bone Marrow	Brain
1	39	30	22	15	11	11
II .	12	28	17	21	11	2
III	23	14	17	9	12	7
IV	22	17	28	7	15	7
<u>V†</u>	26	41	41	24	21	9

Percent of patients. Some patients had more than one site of disease and these data are included in the table.
 † Also includes adrenal involvement per computerized tomography in 4 of 34 (12%) patients.

the greatest percentage of patients with a poor performance status (6%).

Response and survival data are given in tables 3 and 4, respectively. Only one patient in Trial 1 and two patients in Trial II remain alive at 8.4, 6.3 and 7.9 years, respectively. The most serious toxicity has been that of sepsis associated with granulocytopenia resulting in a 4% death rate on the average (range 1-6%).

#### Discussion

A number of clinical observations about these five clinical trials conducted over the past 11 years are worthy of comment. Most striking is the variation in the extent of disease at presentation. Less advanced disease has been observed during the last five years until just recently. Perhaps this is a reflection of a greater awareness of lung cancer in our region which has been associated with both earlier diagnosis and recognition of the availability of potentially effective treatment, particularly for the small cell variant of lung cancer. An example of this phenomenon, perhaps, is the finding of fewer patients with brain metastasis at the time of diagnosis or during pretreatment staging evaluation. This trend has been apparent even though more patients with asymptomatic brain involvement have been discovered through the routine use of computed tomographic scanning rather than using the less sensitive radionuclide scanning technique.16 The recent trend of increasing extent of disease at presentation observed during the last year may in part be a consequence of routine abdominal computed tomographic scanning 15 which heretofore was not a mandatory staging procedure.

Table 3
Response\*

	Overall	Limited	disease		nsive ease			
Trial	CR + PR	PR	CR	PR	CR			
ı	63	47	32	29	26			
II	65	33	39	36	24			
101	74	26	55	39	25			
CAV	64	24	54	26	14			
VCAV	84	28	56	50	34			
IV	63	35	52	20	15			

Percent of patients. Abbreviations: CR, complete response; PR, partial response.

Table 4
Survival\*

Trial	Overall	Limited disease	Extensive disease
1	8.1	9.6	5.3
11	9.1	10.0	8.9
III	10.5	14.6	8.3
CAV	9.4	14.0	6.4
VCAV	11.2	15.0	9.4
IV	9.8	14.0	5.4

Median number of months calculated from time on study until death or last date of contact.

<sup>†</sup> Performance status scale: 0, normal activity; 1, fully ambulatory with symptoms; 2, <50% bedridden and able to care for themselves; 3, >50% bedridden; and 4, 100% bedridden.

In each of the four mature trials (I-IV), an objective response has been observed in the majority of patients with about two-thirds to three-fourths of the patients evidencing a response. The most active regimen in this series has been the VP-16 arm of Trial III in which an objective response occurred in 84% of the patients. This is largely attributed to the greater responsiveness in patients with extensive disease who received treatment on the VP-16 arm of the study; a 34% complete response and 50% partial response were noted in this group. These were the highest complete response and partial response rates for patients with extensive disease seen in any of these trials. Otherwise, the objective response rate in extensive disease patients has been largely static over this period of analysis. In limited disease an increase in the complete response rate over this period from about 30% to 50% may be a reflection of the more aggressive chemotherapy dosages used in later years. The radiotherapy dose-schedule was constant in Trials I-Ill and the overall dosage to the chest in the hemibody radiotherapy protocol (Trial IV) was approximately 3,000 rad or less (2,000 rad conventional + 600 rad upper hemibody).

Despite the improvements in response rates, only moderate increases in survival have occurred during this period. Certainly, there are trends indicating some progress in this area, especially with comparison of the first formal trial conducted in 1974-1976 with those of 1977-1984 (table 4). However, the improved survival during these later years may in part reflect earlier diagnosis and treatment plus improved general medical care as well as, perhaps,

better treatment programs.

The potential for substantially improving survival results in this disease appears to lie in the subgroup of patients who present with rather localized disease. Such patients make up the vast majority of "long-term survivors." Additionally, as more patients are found to have extensive disease through improved diagnostic tests such as computed tomographic scanning and magnetic resonance imaging, it is quite likely that "limited disease" patients with relatively more localized disease will exhibit greater response rates and median survival times than observed in the past. In terms of survival, combined modality treatment with chest radiotherapy and chemotherapy appears to be superior to chemotherapy alone in patients with limited disease.6.7 As found in the majority of reports dealing with small cell lung cancer, however, the chest remains the major site of relapse in each of the trials discussed in the current report. The total dosage used in these trials (3,000 rad) is currently under question since higher doses (≥4,000 rad) appear to be correlated with better local control. 1, 5-7 Currently, a dose of 4,800 rad delivered in a split course (12 fractions × 2) is being used. 15 Certainly small cell lung cancer is a highly radiosensitive disease, but there are many questions concerning optimization of radiotherapy dosage, schedule, and interaction with chemotherapeutic agents which await further investigation in controlled clinical trials.

With improved survival in small cell lung cancer, some late complications of treatment may be recognized. A case of acute leukemia occurred in a patient during Trial III.<sup>17</sup> Bothersome computed tomographic changes of the brain

(atrophy, white matter changes) have been commonly observed upon serial examination of patients treated prophylactically with cranial irradiation<sup>18</sup> and may be associated with chronic neurologic difficulties. The optimal radiation dose-schedule to reduce the high frequency of brain metastasis in this disease and minimize radiation-induced brain injury is unknown. Currently we are using a different dose and fractionation for brain prophylaxis (2,400 rad in 12 fractions) than employed in our previous trials.

Over the past 11 years we have observed slow but steady gains in improving the comfort and survival for patients with small cell lung cancer. This progress has been accomplished through carefully designed clinical trials which have been carried out by the concerted efforts of numerous collaborators and supportive personnel in the fields of medical and radiation oncology. Unfortunately, this disease is a growing health problem and cure is a rare event. An emphasis on preventive medicine in our geographic area accomplished by educators and health care givers through public education about the hazards of tobacco smoking be greatly needed. This is likely to have a much greater long-term impact on this devastating problem than any foreseeable treatment method in the near future.

#### Acknowledgment

We are greatly indebted to the vision and leadership of Dr. Charles L. Spurr who established the Piedmont Oncology Association. By doing so, he brought together many physicians, nurses, physician assistants, statisticians, and a great variety of support personnel in the respective hospitals and clinics in a five-state area which made it possible to conduct investigations with sufficient numbers of patients to answer important

clinical questions about this and other types of cancer.

The patient contribution of the following members of Piedmont Oncology Association in these small cell lung cancer studies is appreciated: Savannah, GA - Dr. Harvey Lebos and Dr. John West; Charlotte Dr. Robert L. Fenning, Dr. Thomas Hauch, Dr. Herman Godwin, Dr. William Porter, Dr. Robert Ruppenthal, and Dr. Alan Thalinger; Gastonia - Dr. Jorge Frank; Greensboro - Dr. Elaine Beed; Goldsboro - Dr. James Atkins; Rocky Mount - Dr. William Bobzien; Rutherfordton - Dr. Robert Harding; Hickory - Dr. Ira Bell; Morganton -Dr. C. H. Lee; Salisbury — Dr. William Black; Spruce Pine — Dr. David Larson; Statesville — Dr. Ruby Grimm; Wilson — Dr. Dudley Anderson; Valdese - Dr. Benjamin Garrou and Dr. Van Rana; Wilmington — Dr. James Wortman and Dr. John Hunter; Winston-Salem Dr. Richard Brodkin and Dr. Marc Slatkoff; Columbia, SC — Dr. Skottowe Fishburne, Dr. James McFarlan, Dr. Francisco Gonsalez and Dr. George Sartiano; Greenwood, SC — Dr. Richard Christian and Dr. William Ramseur; Greenville, SC - Dr. Gerald King; Spartanburg, SC - Dr. James Bearden, Dr. John McCulloch and Dr. Eric Nelson; Bristol, TN - Dr. Ronald Caldwell; Johnson City, TN - Dr. William Kinciad, Dr. Sharon Shipp and Dr. May Votaw; Kingsport, TN - Dr. Ervin A Hire and Dr. Ruth Young; Salem, VA - Dr. Rajiv Jain; Roanoke, VA - Dr. Jack Hutcheson, Dr. Gerald Schertz and Dr. Stephen Kennedy; Winston-Salem (Bowman Gray) — Dr. Charles Spurr, Dr. Fred Richards, Dr. Hyman Muss, Dr. Douglas White, Dr. John Stuart, Dr. Robert Cooper, Dr. Patricia Zekan, Dr. Julia Cruz, Dr. Bayard Powell, Dr. Johnny Craig, Dr. Judith Hopkins, Dr. Robert Capizzi and Dr. Don Jackson.

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#### On Jaw Pain and Blindness

John R. Rice, M.D.

A portion of the delight in practicing clinical medicine comes from the sprinkling of uncommon problems that occasionally enter into our daily activities. A few of these infrequent disorders, unrecognized through lack of familiarity with the scope of potential presenting signs and symptoms, may produce significant consequences for afflicted patients. Along with the fun and challenge of medical practice comes the burden of constant striving to refresh our awareness and ability to recognize those uncommon but highly treatable disorders in whatever guise they may present.

An 86-year-old caucasian woman complained of discomfort in her face and jaw area after having undergone a simple dental procedure. Dental reexamination failed to identify a source for the symptoms and she began to experience enough pain in the jaw and side of her face while chewing that eating became difficult; she began to rely on liquids for nourishment. Her difficulties were further compounded by the emergence of pain during the act of swallowing both solids and liquids.

Four weeks after the onset of facial symptoms, she began to have problems with her vision. She noticed difficulties in putting drops into her husband's eyes, a familiar task she had performed easily in the past, and discovered she had completely lost the sight in her left eye. She was seen by an ophthalmologist and by her personal physician who obtained blood studies which included an erythrocyte sedimentation rate of 49 mm/hr (normal 1-20). No therapy was initiated.

By telephone conversation with the associated physicians, a presumptive diagnosis was made of giant cell arteritis. She was begun on immediate corticosteroid therapy and arrangements were made for her hospitalization and continued therapy with divided-dose intravenous methylprednisolone. Physical examination was unremarkable with the exception of pallor of the optic disc and an absence of light perception and direct pupillary response in the left eye. The temporal arteries were firm to palpation but not tender or nodular. Examination of the temporomandibular joints was normal.

Laboratory studies demonstrated a mild anemia and an erythrocyte sedimentation rate, by the Westergren method, of 83 mm/hr. Serum protein electrophoresis showed increased levels of alpha-2 and gamma globulins. Left temporal artery biopsy (figure 1) demonstrated giant cell arteritis and, at the time of discharge on prednisone 60 mg daily, the erythryocyte sedimentation rate had fallen to 40 mm/hr with some improvement in the patient's problems

with jaw claudication and pain when swallowing.

Once visual loss develops in an elderly individual with giant cell arteritis, there is generally little delay or difficulty in establishing the diagnosis. The challenge for clinicians in dealing with this not uncommon disorder lies in the recognition of its varied early signs and symptoms prior to the occurrence of irreversible sequelae. Blindness, specifically, is rarely the first symptom of giant cell arteritis and adequate, prompt therapy will almost always prevent this unfortunate complication. The first step in making the diagnosis is to be aware of the spectrum of possible presentations of the disease.

#### Giant Cell Arteritis — Common Presenting Complaints

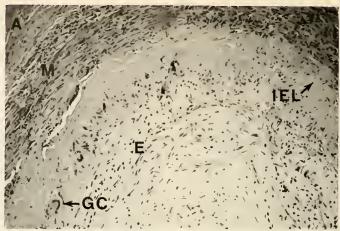
The more common presenting complaints of giant cell arteritis are shown in table 1. The list could be made longer, but it covers the basic types of early symptoms that may occur. Total or partial monocular blindness will occur in up to 50% of patients with untreated giant cell arteritis but is seldom the initial problem. There is usually an interval of days to weeks between presenting symptoms and visual damage. With few exceptions, visual impairment is permanent. It develops, as in the case above, as a result of ischemic injury to the optic nerve or, less commonly, from occlusion of the central retinal artery. Funduscopic examination is usually not especially helpful from a diagnostic standpoint other than to help exclude other potential causes for visual loss.

There are case reports of giant cell arteritis occurring in patients under the age of 50 but 90% of patients in any large series are in their sixties or older. The bulk of patients are caucasian but the disease does develop in blacks often enough to warrant consideration of the diagnosis if the clinical picture is suggestive. Sex ratios are not of clinical value in differential diagnosis.

#### Headache

Headache occurs in about half of patients with giant cell arteritis as an early or presenting symptom of the disease. The pattern of pain may be diffuse or localized but actual scalp tenderness, inflammation or necrosis is the exception rather than the rule. Palpable induration or nodularity of the temporal arteries is sometimes present but is a highly unreliable physical finding. Any type or pattern of headache, new to a patient in the appropriate age bracket, should be carefully evaluated with giant cell arteritis high on the list of diagnostic possibilities. An erythrocyte sedimentation rate, by the Westergren method, constitutes a reasonable screening test for giant cell arteritis in spite of reported rare instances of documented disease in conjunc-

From the Department of Medicine, Duke University Medical Center, Durham 27710.



**Figure 1.** Temporal artery biopsy showing endothelial (E) proliferation, disruption of internal elastic lamina (IEL), giant cells (GC) and inflammatory infiltration of the media (M) and the adventitia (A).

tion with normal erythrocyte sedimentation rate values. It has been well shown that other methods of erythrocyte sedimentation rate determinations are less reliable and should be circumvented.

#### Polymyalgia Rheumatica

Polymyalgia rheumatica is a clinical syndrome characterized by predominantly shoulder and pelvic girdle arthralgias and myalgias. Polymyalgia rheumatica occurs as an early or presenting symptom in approximately 50% of cases of giant cell arteritis. The degree of association between polymyalgia rheumatica and giant cell arteritis is less clear, however, since approximately 50% of patients with polymyalgia rheumatica do not have clinically demonstrable giant cell arteritis. A percentage of patients with polymyalgia rheumatica and no other symptoms or findings to suggest giant cell arteritis will have a positive "blind" temporal artery biopsy; estimates in the literature range up to values of 40-50% but 5-10% seems more realistic based on clinical experience.

In making a diagnosis of polymyalgia rheumatica in the absence of giant cell arteritis, there is no single reliable criterion. Both the age of the patient and Westergren erythrocyte sedimentation rate values should be over 50 or 55. Connective tissues diseases, various forms of vasculitis, malignancies, infections and metabolic diseases have to be excluded and a rapid and total clinical and laboratory response to relatively low doses of corticosteroids (pred-

Table 1
Giant Cell Arteritis — Common Presenting Complaints

- 1. Headache
- 2. Polymyalgia rheumatica
- Jew claudication
- 4. Fever
- 5. Amaurosis fugax
- 6. Dysphagia
- 7. Pulse Asymmetry

nisone 10-15 mg/day) supports the diagnosis. It is unwise to start with high dosages of corticosteroids in this situation since the differential diagnosis of polymyalgia rheumatica is quite broad and high-dose corticosteroid therapy will tend to mask too many of the disorders on the list.

It is difficult to list indications for "blind" temporal artery biopsy in polymyalgia rheumatica. I generally do a biopsy in patients with any suggestion of associated giant cell arteritis and in patients whose response to low-dose corticosteroid therapy is equivocal. A temporal artery biopsy is a relatively simple, benign procedure and can easily be performed on an outpatient. It may be better to have a relatively low threshold for biopsy than to overlook and inadequately treat a patient with giant cell arteritis.

#### Jaw Claudication

True jaw claudication is virtually pathognomonic of giant cell arteritis. In the case report above the patient initially attributed her jaw pain to dental problems. In retrospect, however, she describes having experienced pain in the jaw and side of her face incremented by chewing and relieved by rest. Disease of the temporomandibular joint and disturbances in "bite" tend to cause pain which is either positional or precipitated by a single, strong motion of biting down or clenching the jaw muscles. Facial neuralgias or tic doloreaux produced a dysesthetic or lancinating type of discomfort. Tumors, disease of the sinuses and the so-called "TMJ syndrome" generally produce nonremitting discomfort. Again, patient age and a high index of clinical suspicion are paramount in making a rapid diagnosis. Giant cell arteritis should be included in the differential diagnosis of pain of recent onset in the head, face and neck area in patients over the age of 50 or 55.

#### Fever

Giant cell arteritis is one of the "classical" etiologies for fever of unknown origin in elderly patients. If fever is coupled with loss of weight, malaise and other constitutional complaints the clinical picture may mimic occult malignancy. There may be no symptoms or findings to suggest giant cell arteritis and, again, the diagnosis is made in this situation by "blind" temporal artery biopsy. A point worth mentioning here is the absence of lymphadenopathy in giant cell arteritis; significant generalized or localized adenopathy should suggest consideration of alternative diagnoses.

#### Amaurosis Fugax

Complete visual loss in giant cell arteritis is frequently heralded by a variety of visual complaints including amaurosis fugax. Patients characteristically describe a painless "skim" or "curtain over the eye" which may last only a few seconds and then resolve. Many patients in the giant cell arteritis age range have had eye problems of other etiology and may be unaware of the potential significance of new symptoms. A history of visual disturbance is often obtained only by careful, persistent questioning. Transient visual symptoms in a patient with suspected giant cell arteritis may provide only a few hours or days of warning and should be treated as a medical emergency with immediate parenteral corticosteroid therapy given without delay. An initial 100 mg l.V. dose of hydrocortisone would be reasonable in this situation. Therapy should be continued on an in-hospital basis, parenterally, and without interruption pending completion of evaluation and final diagnostic decisions. There is absolutely no risk of corticosteroid therapy producing a significant alteration in the histological appearance of giant cell arteritis over even a several day span of time pending biopsy.

Whether even higher dosages of "pulse" corticosteroid therapy can afford some hope of reversing optic nerve ischemia in giant cell arteritis has not been established. Such an occurrence is certainly uncommon. Aseptic necrosis of bone, steroid psychosis and other potential risks of such therapy need to be weighed carefully in light of each individual's overall clinical situation. A "cookbook" approach in giant cell arteritis is unsatisfactory. It seems reasonable to suggest, however, that patients with a history of visual disturbance and a clinical picture suggestive of giant cell arteritis be given immediate I.V. corticosteroid therapy in "adequate dosage" and that they be hospitalized for continued parenteral therapy pending biopsy and/or further diagnostic evaluation. Patients with non-visual complaints suggesting giant cell arteritis may often be safely evaluated, biopsied as indicated and treated as outpatients. Starting dosages of corticosteroids in this setting should approximate 1 mg/kg of prednisone either as a single or in divided doses depending on the intensity and nature of the presenting symptoms. Since the levels of corticosteroid therapy can be adjusted downward over the initial treatment period, it is generally wise to err somewhat on the high side if there is doubt about starting doses.

#### Dysphagia

Dysphagia is not an especially common complaint in giant cell arteritis but is included here to emphasize the fact that a variety of head and neck complaints other than jaw claudication may occur in this illness. Any extracranial segment of the branches of the carotid system may be involved with a consequent wide array of sometimes unusual symptoms from resulting ischemia. Tongue claudication, throat pain, deafness, vertigo, and facial nerve palsy are among the described manifestations. As with jaw claudication, these symptoms are due to arterial ischemia rather than to the ill-defined process which produces the arthralgias and myalgias of polymyalgia rheumatica. Improvement in reversible ischemic symptoms is gradual in contradistinction to the dramatic resolution of polymyalgia rheumatica with appropriate treatment.

#### Pulse Asymmetry

Clinically detectable large artery involvement in giant cell arteritis has been estimated to occur in roughly 10% of patients. Bruits are the most common manifestation on physical examination and a few patients present with symptoms or findings resulting from occlusion of the vascular supply to an extremity, usually the upper. Arterial obstruction develops gradually, allowing time for development of collateral flow, and is generally asymptomatic. Large vessel bypass surgery is rarely indicated in this setting. Symptomatic aortitis, aortic dissection, aortic valve disease, and coronary or renal arterial occlusion are all very uncommon manifestations of giant cell arteritis. The relationship of large-vessel giant cell arteritis in caucasians and Takayasu's arteritis in a younger age group of orientals is unclear. It has been suggested that these may represent the same disease process in genetically distinct host populations.

#### Summary

There is no one pathognomonic symptom or finding in giant cell arteritis. Some features are characteristic enough, however, to strongly suggest the diagnosis even in a description given over the telephone as was the case in this elderly patient. The brief review presented here is provided in hope of again reminding the practicing clinician of the varied symptoms of giant cell arteritis and the need to maintain a high level of awareness of this disease with older patients. We can't always be right but we need to try.

#### Suggested Reading

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#### Editor's Note

When the doctor makes an accurate diagnosis of a previously mystifying condition over the telephone, the patient is impressed. Classical jaw claudication comes out as giant cell arteritis. A crunch heard by the patient with each heart beat can be heard by the doctor if the telephone receiver is placed over the patient's mid-sternum. The diagnosis of mediastinal emphysema is made without further ado.

### Focal Motor Seizures in a Thirsty Man

Peter W. Kaplan, M.B., Deirdre M. Collins, M.D., J. Thaddeus Coin, Ph.D., M.D. and Lewis M. Fredane, M.D.

A sixty-year-old right-handed tobacco farmer had been feeling slightly fatigued for one month. For the past week, he had noted a striking increase in thirst and the necessity to urinate. On the day before admission, while working in the tobacco fields, he again felt that he had to pass water and on going to the bathroom noticed a trembling of his right hand that lasted a few seconds. Later that day, he noted the onset of rhythmic tremor of the right arm for several minutes. Throughout the rest of the day he had several similar episodes, often provoked by movement or elevation of the arm. There was no warning before the onset of the movement, and he remained awake throughout and had no bowel or bladder incontinence. There was no weakness or paresthesia of the limb and no involvement of other limbs.

The patient had no previous history of head trauma, seizures or other serious illness. In the emergency room, he was seen to have a sudden onset of rhythmic clonic jerking, starting in the right hand and progressing up the forearm to the pectoral region without involving the head or the other extremities. Throughout the episode, the patient remained alert and maintained preserved speech and verbal recall. There appeared to be no alteration in the level of consciousness. Behavior, affect, short and long term memory and cranial nerve examination were normal. There was mild weakness of the right upper extremity. A stocking distribution, peripheral sensory neuropathy was noted. Coordination testing between episodes was normal. Reflexes were normal and symmetric with the exception of absent ankle jerks.

A complete blood count revealed 12,200 white cells with a normal differential and mean corpuscular volume of 101 μl. Serum electrolytes were normal excepting a glucose of 537 mg/100 ml. Serum calcium and magnesium were normal. Glycosylated hemoglobin was 19% (normal,

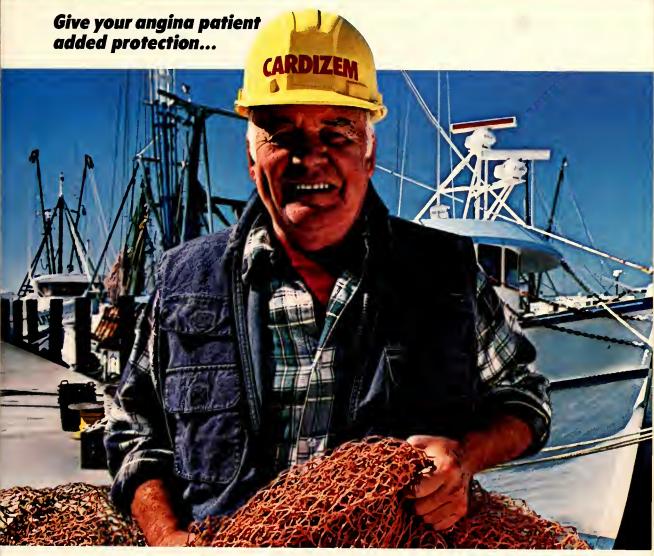
4-7%) and urinalysis showed 2 + albumin with 4 + glucose. Serum folate and vitamin  $B_{12}$  were normal. Enhanced and unenhanced computed tomographic scans of the head revealed several small old infarcts in both frontal and parietal regions, the right cerebellar hemisphere and right pons. Electroencephalography with video monitoring showed repetitive rhythmic theta and epileptiform discharges over the left central region lasting from a minute and a half to two and a half minutes, correlated with focal motor activity. No postictal slowing or other abnormalities were noted.

Focal motor seizures following movement in the right arm continued for 48 hours during which hyperglycemia persisted. With insulin therapy, however, blood glucose values returned to normal and the focal motor seizures ceased without the use of anticonvulsants. The right arm weakness also resolved and the patient was discharged.

Although structural lesions in the brain are the usual cause of focal motor seizures and epilepsia partialis continua, metabolic derangements (commonly nonketotic hyperglycemia of diabetes) are important causes. In one series, over half of the patients had underlying cerebrovascular disease on the appropriate side of the brain. They presented symptomatically with focal motor seizures only when nonketotic hyperglycemia occurred, as was the case in our patient.

Early diagnosis is important, not only because of the high morbidity and mortality associated with hyperosmolar nonketotic diabetes mellitus, but because of the different management of the seizures. The repeated focal motor seizures or epilepsia partialis continua may often be the initial presenting feature in nonketotic hyperglycemia. Seizures may respond to treatment of hyperglycemia and hyperosmolarity alone and in fact are often resistant to anticonvulsant therapy. The rapid recognition and treatment of life-threatening nonketotic hyperglycemia heralded by focal motor seizures should alert the physician to the proper treatment of nonketotic hyperglycemia and the particular aspects of treatment of the seizure disorder.

From the Division of Neurology, Duke University Medical Center, Durham 27710.



## CARDIZEM: FEWER SIDE EFFECTS

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- The lowest incidence of side effects among the calcium channel blockers'
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- Proven efficacy when used alone in angina'.4-6
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#### FEWER SIDE EFFECTS IN ANTIANGINAL THERAPY

#### BRIEF SUMMARY

CAROIZEM® (diltiazem hydrochloride) is a calcium ion influx inhibifor (slow channel blocker or calcium antagonist).

#### INDICATIONS AND USAGE

- 1 Angina Pectoris Que to Coronary Artery Spasm. CAROIZEM is indicated in the treatment of angina pectoris due to coronary artery spasm. CAROIZEM has been shown effective in the treatment of spontaneous coronary artery spasm presenting as Prinz-metal's variant angina (resting angina with ST-segment elevation
- occurring during attacks)

  2 Chronic Stable Angina (Classic Effort-Associated Angina).
  CAROIZEM is indicated in the management of chronic stable angina CAROIZEM has been effective in controlled trials in

reducing angina frequency and increasing exercise tolerance.

There are no controlled studies of the effectiveness of the concomitant use of diffiazem and beta-blockers or of the safety of this combination in patients with impaired ventucular function or conduction abnormalities

#### CONTRAINCICATIONS

CARDIZEM is contraindicated in (1) patients with sick sinus syn-drome except in the presence of a functioning ventricular pacemaker. (2) patients with second or third-degree AV block except in the presence of a functioning ventricular pacemaker, and (3) patients with hypotension (less than 90 mm He systolic).

#### WARNINGS

- Cardiac Conduction, CAROIZEM prolongs AV node refractory periods without significantly prolonging sinus node recovery time periods without significantly prolonging anus node recovery time, except in patients with sick sinus syndrome. This effect may raiely result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (six of 1243 patients for 0.48%). Concomitant use of dilitazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with Prozinetal's angian developed periods of asystole (2.16.5 seconds) after a single dose
- of 60 mg of dilhazem.

  2. Congestive Heart Failure. Although dilhazem has a negative conjective heart relative, intrough untracen has a negative interpretable, the introduced letter in insolated animal Issue preparations, henchydramic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractifity (dp/df). Experience with the use of CARDIZEM alone or in combination with beta blockers in patients with impaired ventricular function is very limited. Caultion should be exercised when using the drift on some hadrons contributions.
- tion should be exercised when using the drug in such patients
  Nypotension Decreases in blood pressure associated with
  CAROIZEM therapy may occasionally result in symptomatic
- A Acute Hepatic Injury In rare instances, patients receiving CAROIZEM have exhibited reversible acute hepatic injury as evidenced by moderate to extreme elevations of liver enzymes (See PRECAUTIONS and ADVERSE REACTIONS.)

#### **PRECAUTIONS**

Seneral CARDIZEM (dilbazem hydrochloride) is extensively metabo lized by the liver and excreted by the kidneys and in bile. As with any new drug given over prolonged periods, laboratory parameters should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of dilitazem were associated with hepatic damage. In special subacute hepatic studies, oral doses of 125 mg/kg and higher in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 20 mg/kg were also associated with hepatic changes, however, these

changes were reversible with continued dosing

Orug Interaction Pharmacologic studies indicate that there may be
additive effects in prolonging AV conduction when using beta-blockers
or digitalis concomitantly with CAROIZEM (See WARNINGS.)

Controlled and uncontrolled domestic studies suggest that con-comitant use of CARDIZEM and beta-blockers or digitalis is usually well tolerated. Available data are not sufficient, however, to predict the effects of concomitant freatment, particularly in patients with left ventricular dysfunction or cardiac conduction abnormalities. In healthy volunteers, diffiazem has been shown to increase serum digoxin levels

Carcinogenesis, Mutagenesis, Impairment of Ferlility A 24-month study in rats and a 21-month study in mice showed no evidence of carcinogenicity. There was also no mutagenic response in in vitro

bacterial tests. No intrinsic effect on fertility was observed in rats.

Pregnancy. Category C. Reproduction studies have been conducted in mice, rats, and rabbits. Administration of doses ranging from five to in mice, fast, and radious, administration of obeser anging from the to the times greater (for a mg/kg basis) than the daily recommended therapeutic dose has resulted in embryo and tetal lethality. These doses, in some studies, have been reported to cause skeletal abnormalities in the perinalal/postnatal studies, there was some reduction in early individual pup weights and survival rates. There was an increased incidence of stillborths at doses of 20 times the human dose or greater.

There are no well-controlled studies in pregnant women, therefore, use CARDIZEM (diltrazem hydrochloride) in pregnant women only if the potential benefit justifies the potential risk to the fetus

Mursing Mothers. It is not known whether this drug is excreted in human milk Because many drugs are excreted in human milk, exercise caution when CARDIZEM is administered to a nursing woman if the drug's benefits are thought to outwergh its potential risks in this

Pediatric Use Safety and effectiveness in children have not been

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been

In domestic placebo-controlled trials, the incidence of adverse reactions reported during CAROIZEM therapy was not greater than that reported during placebo therapy

The following represent occurrences observed in clinical studies which can be at least reasonably associated with the pharmacology of calcium influx inhibition. In many cases, the relationship to CARDIZEM has not been established The most common occurrences, as well as their frequency of presentation, are edema (2.4%), headache (2.1%), nausea (1.9%), dizzness (1.5%), rash (1.3%), asthema (1.2%), AV block (1.1%). In addition, the following events were reported infrequently (less than 1%) with the order of presentation corresponding to the relative frequency of occurrence

Cardiovascular Nervous System Gastrointestinal Flushing, arrhythmia, hypotension, bradycardia, palpitations, congestive heart lailure, syncope Paresthesia nervousness, somnolence, tremor, insomnia, hallucinations, and amnesia

Constipation, dyspepsia, diarrhea, vomiting, mild elevations of alkaline phosphatase, SGOT, SGPT, and LOH

**Oermatologic** 

Pruritus, petechiae, urticaria, photosensitivity Polyuma, nocturia

The following additional experiences have been noted A patient with Prinzmetal's angina experiencing episodes of vaso-spastic angina developed periods of transient asymptomatic asystole oximately five hours after receiving a single 60-mg dose of

The following postmarketing events have been reported infrequently in patients receiving CAROLEEM erythem aufilitione, leukopeina, and extreme elevations of alkaline phosphatase, SGOT, SGPT, LOH, and CPK. However, a definitive cause and effect between these events and CARDIZEM therapy is yet to be established.

#### OVERDOSAGE OR EXAGGERATED RESPONSE

Overdosage experience with erayonist.

Overdosage experience with oral diffusem has been limited. Single oral doses of 300 mg of CAROLIZEM have been well tolerated by healthy volunteers. In the event of overdosage or exaggerated response, appropriate supportive measures should be employed in addition to gastic. lavage. The following measures may be considered

Bradycardia

Administer atropine (0.60 to 1.0 mg). If there is no response to vagal blockade, administer isoproterenol cautiously.

Nigh-Degree AV Block

Treat as for bradycardia above Fixed high-degree AV block should be treated with cardiac pacing

Cardiac Failure Hypotension

Administer inofropic agents (isoproterenol, dopamine, or dobutamine) and diuretics Vasopressors (eg. dopamine or levarterenol bitartrate)

Actual treatment and dosage should depend on the severity of the linical situation and the judgment and experience of the treating physician

projection. The oral LO<sub>50</sub>'s in mice and rats range from 415 to 740 mg/kg and from 560 to 810 mg/kg, respectively. The intravenous LO<sub>50</sub>'s in these species were 60 and 38 mg/kg, respectively from 60 and 10.50 mg/kg respectively from 60 and 10.50 mg/kg. while lethality was seen in monkery at 360 mg/kg. The torust close in man is not known, but blood levels in excess of 800 ng/ml have not been associated with toxicity.

#### NOTABLE STRING A DAY SASSOD

ODSAGE AND ADMINISTRATION

Exertional Angina Pectors Bue to Atheroscierotic Coronary Artery disease or Angina Pectoris at Rest Que to Coronary Astery Gisease or Angina Pectoris at Rest Que to Coronary Astery Spasm. Obsage must be adjusted to each patient's needs Stating with 30 mg four times daily before meals and at bedtime, dosage should be increased gradually (geven in divided doses three or untimes daily) at one- to two-day intervals until optimum responses obtained Athough Individual patients may respond to any dosage level, the average optimum dosage range appears to be 180 to 240 mpt/day. There are no available data concerning dosage recommendations. age level, the average optimum dosage range appears to be 180 to 240 mg/day. There are no available data concerning dosage requirements in patients with impaired renal or hepatic function. If the dwig must be used in such patients, titration should be carried out with particular caution

#### Concomitant Use With Other Antianginal Agents:

- Concomment user with order Antianagnia agents:

  1 Sublingual RT iff may be taken as required to abort acute anginal attacks during CAROUZEM therapy

  2 Prophystactic Mirrate Therapy CAROUZEM may be safely co-administered with short- and long-acute in partial spatial representations of the companies of the comp ness of this combination
- Beta-blockers. (See WARNINGS and PRECAUTIONS )

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See complete Professional Use Information before prescribing

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Another patient benefit product from



## Intracavernous Self-injection of Papaverine and Regitine for the Treatment of Organic Impotence

Edward O. Janosko, M.D.

NCE the diagnosis of organic impotence is established, the patient's option of therapy usually is a penile prosthesis. All penile prostheses require a surgical procedure with its attendant risks, postoperative discomfort and loss of work. Although many patients are eager to obtain potency, some are reluctant to undergo surgery and deprive themselves of complete sexual functioning. In 1982 Virag described the use of intracavernous injection of papaverine to produce an artificial erection, and in 1983 Brindley produced penile erection with the intracavernous injection of phenoxybenzamine.2 Zorgniotti and Lefleur in 1985 reported the induction of penile erection in patients with vasculogenic impotence with a combination of papaverine and phentolamine by intracavernous auto-injection.3 This report reviews our experience and observations with self-injection of the corpora cavernosa with papaverine and phentolamine for the treatment of organic impotence that is vascular, neurologic and undefined in origin.

#### Method

Patients who had poor or absent nocturnal erections by history, by snap gauge or by nocturnal penile tumescence monitoring were studied with Doppler ultrasound to obtain a penile-brachial index, and by vibratory neurologic testing to determine sensory deficits in the penis. Impotence was established by these studies together with a history and physical examination. Patients were considered to have vasculogenic impotence if their penile brachial doppler pressure index was less than 0.8. Patients were considered to have neurologic impotence if their vibratory sensory threshold was greater than 10 dial units by Bio-thesiometer testing and if they had a normal penile brachial index. Some patients were considered to have both neurologic and vascular impotence. A few patients had undefined organic impotence. A total of 21 patients between the ages of 29 and 69 were diagnosed as having organic impotence. Table 1 includes the etiology of the impotence in the pop-

After informed consent, a staff urologist, using a 27 g needle, injected 0.5-1.0 cc of a mixture containing 30 mg/cc of papaverine and 0.5 mg/cc of phentolamine mesylate

into one of the corpora cavernosa on the penile shafts of the 21 patients. Attention was given to perforating the tunica albuginea and to avoiding the neurovascular bundle. The urologist then categorized the erection for tumescence and rigidity. All non-tumescent or non-rigid penises received the maximum of 1.0 cc. Sixteen patients obtained good erections with the injection and all were offered the opportunity to participate in the self-injection study or to be treated with a penile prosthesis. Two patients decided against any therapy. Fourteen patients entered the study. Only two patients requested a prosthesis when given the option of non-surgical therapy and both of these patients were included in the self-injection study on a temporary basis since work duties would not allow surgical therapy for several months. One patient was lost to follow up.

After additional informed consent was obtained, the patients were instructed by a urologist in sterile self-injection of the corpora cavernosa with a tuberculin syringe with a 27 g needle. Specific instructions were given to perforate the tunica albuginea and to avoid the neurovascular bundle and superficial veins. They were to alternate sides of the injection site and to induce an erection no more than every other day, and they were given enough medication for approximately four weeks. The patients kept a log of the time length of their erections and they were followed for 3 to 8 months on two to four-week intervals. The amount of medication injected was altered at follow-up visits depending on the patient's reports of the quality and time length of the erection. All patients were instructed to call if an erection lasted longer than four hours.

#### Results

Table 1 summarizes the patients by age, medical diagnosis, presumed etiology of impotence, penile-brachial index, Bio-thesiometer sensory index, dose of injection, and results of the initially screened group. With the initial injection, tumescence occurred with five minutes and rigidity occurred within 8-10 minutes if tumescence occurred. Patients who did not respond well to the injection usually had severe vascular disease as indicated by their penile-brachial index or rarely had a cavernosal venous leak. Neurologically impotent patients responded to lower doses of the mixture.

Table 2 summarizes the self-injection patients. These

From Greenville Urology Clinic, 2 Doctors' Park, Greenville 27834.

Table 1 **Evaluation of Screened Patients** 

Patient	Age	Medical Dx Impotence Dx		Penile Brachial Index	Sensory Index	Test Dose (cc)	Results	
1	62	S/P Urethral Surgery	Undefined	.90	ND	1.0	poor	
2	45	Diabetes	Vascular	.63	ND	1.0	poor	
3	69	Diabetes	Vascular	.40	ND	1.0	poor	
4	64	Hypertension	Vascular	.70	ND	1.0	good	
5	67	S/P Prosthesis	Both	.75	20	1.0	poor	
6	66	S/P Radical prostatectomy	Neurologic	.84	20	1.0	fair	
7	66	Diabetes	Undefined	.90	7	1.0	fair	
8	60	Diabetes	Both	.75	20	.80	good	
9	51	Diabetes	Neurologic	.94	13	.50	good	
10	43	None	Undefined	.80	4	.25	good	
11	54	Diabetes Peyronies	Both	.75	20	1.0	good	
12	38	Multiple Sclerosis	Neurologic	1.0	25	.50	good	
13	53	Renal failure	Vascular	.70	7	1.0	good	
14	44	Paraparesis	Neurologic	.95	30	.50	good	
15	51	Peyronies Diabetes	Both	.70	20	1.0	good	
16	46	Diabetes	Undefined	1.0	6	.50	good	
17	61	Hypertension	Vascular	.68		1.0		
18	58	Hypertension	Undefined	.80	8 7	1.0	good good	
19	55	None	Vascular	.70	3	.50	good	
20	57	None	Vascular	.70	5	.50		
21	29	Paraplegic	Neurologic	.80	>50	.50	good good	

Table 2 Results of Patients in Study

7	8	9	10	11	12	13	16	17	18	19	20	21
1	s	s	b	s		s	1	h		h	•	b
.25	.50	.25	1.0	.30	.25	1.0	1.0	.50	.20	.50	.50	.25
_	_	si	_	_	_	si		-	si	_	_	_
na	n	n	n	n	na	n	n	n	n	m	n	na
0	2	1	1.75	1	3-4	1-2	2	2	.5	2-4	2	2-3
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b = both sitting and lying

si = subcutaneous injection na = not applicable

n = no ejaculatory effect on erection

patients reported tumescence and rigidity within 10 minutes of self-injection with erections lasting from 2-4 hours. All patients reported successful coitus and, interestingly, erections were either unchanged or became slightly less rigid temporarily following ejaculation. Partner stimulation increased the onset of the erection and increased the rigidity in some patients. No untoward systemic effects were noted. There were no incidents of syncope, hypotension, or hepatic dysfunction. There have been no infections of the injection sites. Patients found that the sitting position was easier for self-injection than the lying position. Most patients opted to inject themselves rather than have their sex partner inject them except when this was impossible, e.g., the patient with multiple sclerosis. Diabetics were easier to instruct because of their familiarity with insulin injections. Finally, all sex partners interviewed, except one, reported erections satisfactory for intercourse. The exception was the wife of the one patient who experienced pain with the injection.

The most common complication was the inability to produce the erection at home. All of these instances were found to be caused by poor injection technique (the tunica albuginea was not penetrated, resulting in a subcutaneous injection), and with re-education these patients' erections with injection were re-established. One patient experienced priapism three weeks into therapy. He had not altered his dose, which had been effective without priapism, and the etiology is unclear. After presenting with priapism 12 hours after injection, he was successfully treated with cavernous irrigation with a 1:1,000,000 epinephrine solution. He has resumed the injections at a lower dose without further complication so far.

Three patients have discontinued the self-injection therapy. Two patients have discontinued because of dissatisfaction: one because of pain with the injection who has subsequently been implanted and another with a severe peripheral neuropathy who experienced no penile satisfaction or pleasure and has not requested a prosthesis. The

third patient originally requested a prosthesis and was in the study temporarily; he is now ready for an implant. All but one patient were satisfied with the quality of the erection and sexual function. One of the patients who requested self-injection therapy temporarily has now elected to continue rather than have a penile prosthesis placed.

#### Discussion

Because the precise neurovascular anatomy and physiology of erection remains unclear, the mechanism of erection is not totally understood. However three important components have been described: neurologic, arterial, and venous.<sup>4-10</sup>

A possible system of events for the normal induction of impotence is that with psychic or physical stimulation, the nervi erigentes emit neurotransmitters which cause active corporal cavernosal trabecular smooth muscle relaxation. This causes decreased peripheral resistance in the corpora resulting in vasodilation of the cavernosal arteries and subsequent filling of the corpora cavernosa with blood. The venous outflow from the corpora cavernosa may decrease during this time and the erection occurs. Interruption of any of these three components can result in impotence.4-11 Ertekin and Reel5 reported patients with neurological impotence. McDougal and Jeffrey reported patients with vascular impotence who were rendered potent by microsurgical penile artery bypass grafting. And Wespes and Schulman9 have reported 16 patients with impotence resulting from venous leaks who were cured with deep dorsal vein ligation.

The neurotransmitters resulting in erection are still unclear, 12 although alpha-adrenergic blockage can induce tumescence in man<sup>2</sup> and alpha agonists can reverse erections in the cat.13 The finding of significant amounts of alpha receptors in the cavernosal tissue<sup>14</sup> had led Van Arsdalen and Wein to suggest that the corporal arteries are under chronic vasoconstriction,15 presumably from sympathetic activity. Wagner has suggested that during erection there is active relaxation of the trabecular smooth muscle of the corpora cavernosa16 which allows blood to fill the corpora resulting in tumescence. The neurotransmitter involved with this latter action is unknown, but VIP has received recent attention. 16, 17 Phentolamine is an alpha adrenergic blocking agent and papaverine is a smooth muscle relaxant. 18, 19 This may explain the erectogenic properties of this drug combination.

Patients who entered our self-injection program have enthusiastically embraced it. This mechanism for inducing an erection does not require an operative procedure; the injection technique is easily learned; the erection is normal as compared with the artificial erection of a penile prosthesis; and no major side effects, except for one episode of priapism, have been noted. There was only one dropout from the group because of pain from the injection.

Further studies are continuing as further experience is obtained. Although we have seen minimal complications, priapism and infection may occur and unknown side effects may result. We recommend that until further information becomes available, the drugs not be administered to patients predisposed to priapism, e.g., sickle cell patients and those on phenothiazines, or to patients with hepatic dysfunction. Therapy should be supervised by urologists familiar with evaluating impotency and with the care of potential complications. Informed consent is mandatory especially since these drugs are not approved for this specific use.

#### Acknowledgment

I am grateful to J. Richard Gavigan, M.D. and Emmett J. Walsh, Jr., M.D. for assistance in the clinical management of these patients.

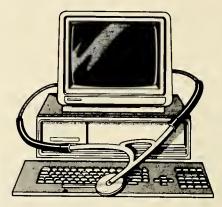
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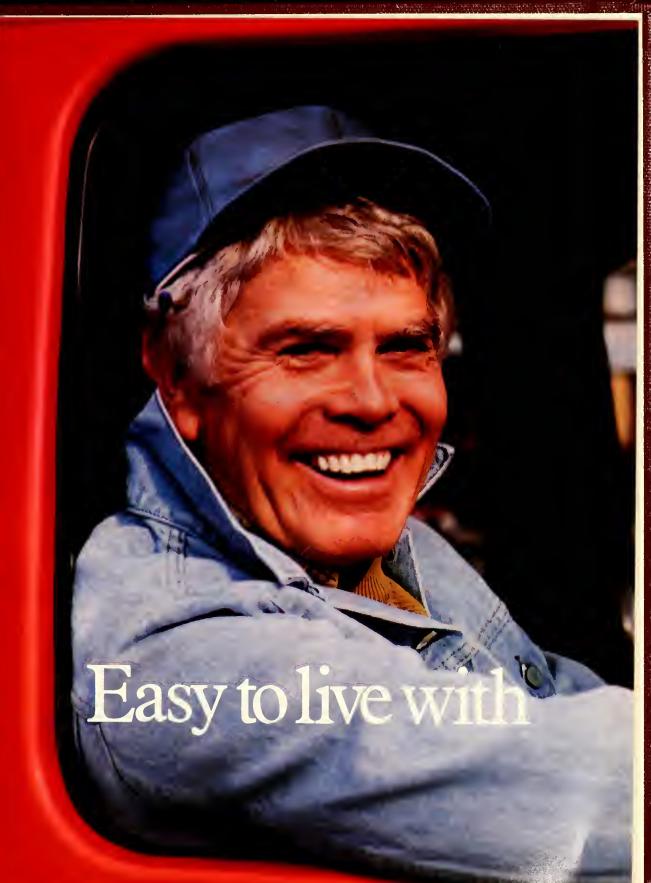
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 INDERAL LA avoids the sharp peaks seen with atenolol

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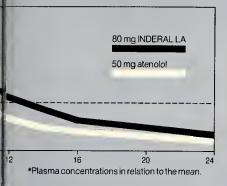


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As with all fixed-combination antihypertensives, INDERIDE LA is not indicated for the initial treatment of hypertension.

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#### CONTRAINDICATIONS

Propranolol hydrochloride (INDERAL ® LA): Propranolol is contraindicated in 1) cardiogenic shock, 2) sinus bradycardia and greater than first degree block, 3) bronchial asthma, 4) congestive heart failure (see WARNINGS) unless the failure is secondary to a tachyarrhythmia

Hydrochlorothiazide: Hydrochlorothiazide is contraindicated in patients with anuria or hypersensitivity to this or other sulfonamide-derived drugs

#### WARNINGS

WARNINGS
Propranolol hydrochloride (INDERAL® LA): CARDIAC FAILURE Sympathetic stimulation may be a vital component supporting circulatory function in patients with congestive head railure, and its inhibition by beta blocked may precipitate more severe failure. Although beta blockers should be avoided in overt congestive heart failure, if necessary, they can be used with close follow-up in patients with a history of failure who are well compensated, and are receiving digitals and diurefices. Beta-adrenergic blocking agents do not abolish the inotropic action of digitals on heart muscle
IN PATIENT'S WITHOUT A HISTORY OF HEART FAILURE, continued use of beta blockers can, in some cases learn to cardiac failure. Therefore, at the first some is wisnown theart failure.

some cases, lead to cardiac failure. Therefore, at the first sign or symptom of heart failure, the patient should be digitalized and/or treated with diuretics, and the response observed closely, or propriated should be discontinued (gradually, if possible).

IN PATIENTS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina IN PAILENIS WITH ANGINA PECTORIS, there have been reports of exacerbation of angina and, in some cases, myocardial infarction following abrypt discontinuance of propranolol therapy. Therefore, when discontinuance of propranolol is planned the dosage should be gradually reduced and the patient carefully monitored in addition, when propranolol is prescribed for angina pectoris, the patient should be cautioned against interruption or cessation of therapy without the physicians advice, if propranolol therapy is interrupted and exacerbation of angina occurs, it usually is advisable to reinstitute propranolol theraps. Since lake other measures appropriate for the management of unstable angina pectors. Since coronary artery disease may be unrecognized, it may be prudent to follow the above advice in patients considered at risk of having occult atherosclerotic heart disease who are given propranolol for other indications.

THYROTOXICOSIS Beta blockade may mask certain clinical signs of hyperthyriodism Therefore, abrupt withdrawal of propranolol may be followed by an exacerbation of symptoms of 
hyperthyriodism, including thyroid storm Propranolol does not distort thyroid unchion tests 
IN PATIENTS WITH WOLF-PARKINSON WHITE SYNDROME, several cases have been reported in which, after propranolol, the tachycardia was replaced by a severe bradycardia requiring a 
demand pacemaker in one case this resulted after an initial dose of 5 mg propranolol 
MAJOR SURGERY The necessity or desirability of withdrawal of beta-blocking therapy prior to 
major surgery is controversial it should be noted, however, that the impared ability of the heart to 
respond to reflex adrenergic stimuli may augment the risks of general anesthesia and surgical 
procedures.

Nonellergic Bronchospasm (eg, chronic bronchitis, emphyseme)—PATIENTS 
WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS 
INDERAL should be administered with caution, since it may block bronchodilation produced by 
endogenous and exogenous catecholamine stimulation of beta receptors 
DIABETES AND HYPOGLYCEMIA Beta addrenergic blockade may prevent the appearance of 
certain premonitory signs and symptoms (pulse rate and pressure changes) of acute hypoglycemia in lable insulin-dependent diabetes in these patients, it may be more difficult to adjust 
the dosage of insulin Hypoglycemic attacks may be accompanied by a precipitous elevation of 
blood researce.

hydrochlorothiezide: Thiazides should be used with caution in severe renal disease. In patients with renal disease, thrazides may precipitate azoternia. In patients with impaired renal function, cumulative effects of the drug may develop.

Thiazides should also be used with caution in patients with impaired hepatic function or progressive liver disease, since minor alterations of fluid and electrolyte balance may precipitate hepatic country.

progressive liver disease, since minor alterations of third and electrolyte balance may precipitate hepatic come.

Thiazides may add to or potentiate the action of other antihypertensive drugs. Potentiation occurs with ganglionic or peripheral attenergic blocking drugs.

Sensitivity reactions may occur in patients with a history of altergy or bronchial asthma. The possibility of exacerbation or activation of systemic lupus erythematosus has been reported.

#### PRECAUTIONS

Propranolol hydrochloride (INDERAL® LA): GENERAL Propranolol should be used with

Propranolal hydrochloride (INDERAL® LA): GENERAL Propranolal should be used with caution in patients with impaired hepatic or renal function. Propranolal is not indicated for the treatment of hypertensive emergencies.

Beta adrenoreceptor blockade can cause reduction of intraocular pressure. Patients should be told that propranolal may interfere with the glaucoma screening test. Withdrawal may lead to a return of increased intraocular pressure. CLINICAL LABORATORY TESTS. Elevated blood urea levels in patients with severe heart disease, elevated serum transaminase, alkaline phosphatase, lactate dehydrogenase. DRUG INTERACTIONS. Patients receiving catechotamine-depleting drugs, such as reserpine should be closely observed if propranolal is administered. The added catecholamine blocking action may produce an excessive reduction of resting sympathetic nervous activity, which may result in hypotension, marked bradycardia, vertigo, syncopal attacks, or orthostatic hypotension. CARCINOGENESIS, MUTAGENESIS, IMPAIRMENT OF FERTILITY Long term studies in aminist have been conducted to evaluate tonc effects and carcinogenic potential. In 18 month studies, in both rats and mice, employing doses up to 150 mg/kg/day, there was no evidence of significant drug-induced toxicity. There were no drug-related tumorigenic effects at any of the dosage levels. Reproductive studies in animals did not show any impairment of tertility that was attributable to the drug.

forg drug PREGNANCY Pregnancy Category C Propranolol has been shown to be embryotoxic in animal PREGNANCY Pregnancy Category C Propranolol has been shown to be embryotoxic in animal proprand to the proprand studies at doses about 10 imes greater than the maximal recommended thurman dose. There are no adequate and well-controlled studies in pregnant women. Proprianolol should be used during pregnancy only it be potential benefit justifies the potential risk to the fetus.

#### Once-daily NDERIDE LA

80 mg, 120 mg, or 160 mg, and hydrochlorothiazide, 50 mg



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160/50

NURSING MOTHERS Propranolol is excreted in human milk. Caution should be exercised when propranolol is administered to a nursing mother FEDMATRIC USE Safety and effectiveness in children have not been established Hydrochlorothiazide: GENERAL. Periodic determination of serum electrolytes to detect possible electrolyte imbalance, nace should be performed at appropriate intertory termination and urrine imbalance, namely. Hyponatrema, hypochloremic alkalosis, and hypokalema. Serum and urrine electrolyte determinations are particularly important when the patient is vomiting excessively or receiving parenteral fluids. Medication such as digitalis may also influence serum electrolytes. Warning signs irrespective of cause are Dryness of mouth, thirst, weakness, lethargy, drowsiness, restlessness, muscle pans or cramps, muscular fatigue, trypotension, oliguria, tachycardia, and gastrointestinal disturbances such as nausea and vomiting.

gastrointestinal disturbances such as nausea and wornting. 
Hypokalema may develop, especially with busk diuresis, when severe currhosis is present, or during concomitant use of corticosteroids or ACTH. 
Interference with adequate oral electrolyte intake will also contribute to hypokalemia Hypokalemia can sensitize or exaggerate the response of the heart to the toxic effect of utgitals (eg., increased ventricular irritability). Hypokalemia may be avoided or treated by use of potassium supplements, such as foods with a high potassium content. 
Any chloride deficit is generally mild and usually does not require specific treatment, except under extraordinary circumstances (as in liver or renal disease). Diutional hyponatremia may occur in edematous patients in hio weather, appropriate therapy is water restriction, rather than administration of salt, except in rare instances when the hyponatremia is life-threatening in actual salt depletion, appropriate terpaid concernent is the threapy of choice.

Hyperuncemia may occur or trank gout may be preopitated in certain patients receiving thiazide therapy.

Insulin requirements in diabetic patients may be increased, decreased, or unchanged Diabetes mellitus which has been latent may become manifest during thiazide administration. If progressive renal impairment becomes evident, consider withholding or discontinuing diuretic

It progressive terain popular therapy.

This progressive terain passive the sum PBI levels without signs of thyroid disturbance. This progressive the sum of the parathyroid gland with hypercal cernia and hypophosphatemia have been observed in a few patients on prolonged thazide therapy. The common complications of hyperparathyroidsm, such as renal lithiasis, bone resorption, and peptic ulceration, have not been seen. This progressive the discontinued before corrupt out tests for parathyroid function.

resorption, and peptic ulceration, have not been seen. Thiszides should be discontinued before carrying out tests for parathyroid function. DRUG INTERACTIONS. Thiszide drugs may increase the responsiveness to tubocuranne. The antihypertensive effects of thiszides may be enhanced in the postsympathectomy patient. Thiszides may decrease arterial responsiveness to norepinephrine. This diminution is not sufficient to preclude effectiveness of the pressor agent for therapeutic use. PREGNANCY Pregnancy Category C. Thiszides cross the placental barrier and appear in cord blood. The use of thiszides in pregnancy requires that the anticopated benefit be weighed against possible hazards to the fetus. These hazards include fetal or neonatal jaundice, thrombocytopenia, and possibly other adverse reactions which have occurred in the adult! NURSING MCTHERS. Thiszides appear in human milk. It use of the drug is deemed essential, the patient should stop nursion.

the patient should stop nursing
PEDIATRIC USE Safety and effectiveness in children have not been established

#### **ADVERSE REACTIONS**

ADVERSE REACTIONS
Propranolol hydrochloride (INDERAL® LA): Most adverse effects have been mild and transent and have rarely required the withdrawal of therapy
Cardiovascular Bradycardia, congestive heart failure, intensification of AV block, hypotension; paresthesia of hands, thrombocytopenic purpura, affend insufficiency, usually of the Raynaud

patristreare or randomers of the patricipal 
Gastrointestinal<sup>\*</sup> Nausea, vomiting, epigastric distress, abdominal cramping, diarrhea, consti-pation, mesenteric arterial thrombosis, ischemic collits. Aflergic Pharyngtis and agranulocylosis, erythematious rash, fever combined with aching and sore throat, laryngospasm and respiratory distress. Respiratory Bronchospasm

Hematologic Agranulocytosis; nonthrombocytopenic purpura, thrombocytopenic purpura Auto-Immune In extremely rare instances, systemic lupus crythematosus has been reported Miscellaneous Alopecia, LE-like reactions, psoriasiform rashes, dry eyes, male impotence; and Perronles disease have been reported rarely Oculomucocutaneous reactions involving the skin, serous membranes, and conjunctivae reported for a bela blocker (practolol) have not been associated with propranolol

associated with proprianolol 
Mydrochlorothiazide: 
Gastrointestinal Anorexa, gastric irritation, nausea, vomiting, cramping, diiarrhea, constipation, 
jaundice (intrahepatic cholestatic jaundice), pancreafitis, saladenitis. 
Central Nervous System Dizziness, vertigo, paresthesias, headische, xanthopsia 
Hematologic Leukopena, agranulico/toppena, aglastic anemia. 
Cardiovascular Orthostatic hypotension (may be aggravated by alcohol, barbiturates, or 
narchicol.

narcorics).

Hypersensitivity Purpura, photosensitivity, rash, urticaria, necrotizing angilis (vasculitis, cutaneous vasculitis), lever, respiratory distress, including pneumonitis, anaphylactic reactions.

Other. Hyperglycemia, glycosuria, hyperunicemia, muscle spasm, weakness, restlessness, transient blurred vision.

Whenever adverse reactions are moderate or severe, thiazide dosage should be reduced or

therapy withdrawn
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Marc D. Feldman, M.D.

BENZODIAZEPINES have become the predominant anxiolytic and sedative-hypnotic agents in medical practice. Areas of additional use include premedication in anesthesia and treatment of alcohol withdrawal states, seizure disorders, tetanus, and spasticity in upper motoneuron disease and cerebral palsy. Standard texts and clinical wisdom have mandated attention to unwanted "paradoxical effects" in assessing patients' responses to these medications.

Paradoxical reactions to benzodiazepines are defined as adverse psychological and physical effects that differ from common side effects, such as drowsiness and ataxia, in that they do not represent a more intense expression of the desired pharmacologic results.1 Since 1960, when irritability and hyperactivity were described in patients receiving chlordiazepoxide,2 a myriad of other apparently paradoxical responses has appeared in the literature. In one early report six patients without prior psychiatric histories who received high-dose diazepam for medical conditions showed severe, reversible tremulousness, apprehension, and insomnia within 30 days of beginning the medication.3 In another study, seven depressed patients experienced an exacerbation of suicidal ideation, with two completed suicides, shortly after starting diazepam in therapeutic doses;4 the suicidal ideation, observed by others and reported as ego-dystonic,3 abated promptly after the drug was discontinued. While responses ranging from irritability and verbal hostility to rage and physical violence have been most frequently associated with diazepam and chlordiazepoxide,5.6 other benzodiazepines have been implicated as well, such as clonazepam,7 clorazepate,5 temazepam,8 and clobazam.9 Case reports have involved populations as diverse as schizophrenics, 2 anxious outpatients, 10 and normal college students.6 The methods utilized in documenting increased aggressiveness after the initiation of benzodiazepine treatment have been varied, and include psychological tests, observer rating scales, and anecdotal accounts.6 For unknown reasons, oxazepam appears less likely to induce hostility than diazepam or chlordiazepoxide.10 Furthermore, men may be less prone than women or children to increased hostility as a benzodiazepine reaction.7

Benzodiazepines, including those traditionally marketed as hypnotics, have also been reported to have caused paradoxical sleep disturbances and hypnagogic experiences; the latter are defined as vivid dreams or hallucinations at sleep onset representing premature REM sleep. Van der Kroef<sup>11</sup> has noted nightmares, restlessness, and hypnagogic hallucinations associated with triazolam in patients both with and without psychiatric illnesses. Nightmares have additionally been seen with nitrazepam, 12 temazepam, 8 and flurazepam, 12 especially in the first week of use. Again contrasting their standard clinical action, anticonvulsant benzodiazepines may in fact induce motor stimulation and precipitate seizures. 12 Other less well-defined paradoxical effects attributed to benzodiazepines in isolated accounts include episodes of "petty crime . . . in people with previously unblemished characters" and a continous fear of going insane. 11

It has been postulated that paradoxical reactions are related more to personal or environmental factors than to pharmacologic activity per se.<sup>1,6</sup> It is known that medications with disinhibitory effects can lead to hostility in individuals with poor impulse control;<sup>6</sup> rage reactions may thus be viewed as predictable rather than paradoxical effects in some patients because of a benzodiazepine-mediated "release of 'anxiety-bound' hostility." <sup>14</sup> This anger and hostility may become apparent only when subjects are confronted with environmental frustration. Conversely, although early researchers often reported on psychiatricallyill patients using high doses of benzodiazepines, ostensibly-normal individuals on usual doses have shown paradoxical responses as well, raising the possibility of a primary benzodiazepine effect in certain persons. <sup>12</sup>

The incidence of paradoxical effects is uncertain, though it appears to be low. Similarly, the overall clinical significance in terms of prescribing practices has not been firmly established. Treatment of paradoxical reactions has generally been effected by discontinuing the medication or adjusting the dosage downward. Others recommend increasing the dose or stopping the benzodiazepine and reintroducing it slowly. Recommendations for avoiding paradoxical effects altogether include strict adherence to maximal recommended dosages; acutious administration in apparently high-risk patients, such as the elderly and those with vascular disease or depression; the use of oxazepam rather than other benzodiazepines in anxious patients with a history of aggressive behavior; and avoidance of benzodiazepines in anxiety that is only mild.

In summary, benzodiazepines are a widely-used class of drugs which infrequently have unwanted and pharmacologically-unanticipated results. Recognition of these 'paradoxical' effects may permit judicious dosage adjustment or drug substitution as a way to maximize their clinical value.

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#### The Medicine Is Bitter

James P. Weaver, M.D.

FOR a member of a group who, over the years, has recommended to many patients that the "medicine may be bitter, but the cure is worth it," I continue to be surprised by the failure of the medical profession to recognize the trends that are slowly eroding the very basis of the delivery of health care and to take the medicine that is so necessary to begin to cure the malady. If we as a profession agree that the basis of the strength of the medical system in this country rests on the strength of the physician-patient relationship, I believe there is a bitter medicine available to us if we will take the time to use it and, for the eventual salvation of medicine, I suggest we take the cure.

It came to my attention when I had a patient visit my office with a problem that required "precertification" from the insurance company prior to admission to the hospital. He was an intelligent man, and I thought I would try something new with him. I told the patient that his insurance policy required precertification prior to hospitalization, and that he would have to get the certification. He agreed, and it was easily done. Once I had required the patient to obtain the precertification a whole spectrum of possibilities opened up which contain some messages of general importance.

First, it is more appropriate that the patient do his own precertification. It is his policy, or the policy that his employer has purchased for him, and it is only proper that he deal with the inconveniences imposed by his insurance company. In my recent circumstance, the patient clearly understood this.

Second, my relationship with my patient was strengthened by this move, for I was able to tell him that I would help him in any way that I could; that reinforced the appropriate relationship of me to the patient, and not me to the insurance company. I really think the patient is more comfortable thinking that the doctor is on his side.

Third, I realized that it is more effective when the insurance company is forced to deal with the "customer." The doctor is not the customer, and long waits on the phone, abruptness, and unusual delays offer us very little recourse. Our patients are actually their customers and one might expect a more congenial response when dealing with the one who pays the bills.

Finally, I realized that the insurance companies are happy to treat me like a business, and use all the weapons at their disposal to control, manipulate and limit my practice, my income, and finally the care of my patients. It is only if I take the time to strengthen the relationship with my patients and place it in proper perspective that that cannot be done.

The very act of taking the precertification process from the patient makes a statement that we have a basic and primary relationship with the third party payor. I am certain that with some third party payors it is true that a relationship of that sort exists, but when no contract has been signed, and no formal agreement has been made, there is no agreement with the third party, and the main relationship is with the patient.

I cannot believe the willingness with which doctors have fallen in line with the demands of third party payors for precertification and extension of days, even in the face of no signed contract or agreement between us. How can insurance companies be so careful that no services are "given away" from their point of view and at the same time assume that physicians who have no contractual relationship with them will give of their time and the time of their staff to help the third party payors administer their policy with their client? The insurance company's ability to sell policies is enhanced by the inclusion of a precertification clause in the policy. The periodic checks with the doctor or his staff on the hospital course also contribute to the overall marketability of their policies. I don't see why I should help the insurance companies sell insurance at my expense.

It is the patient or his employer who purchases a health insurance policy. The lavishness of the benefits is related, as is everything else in life, to the amount the customer is willing to pay for the particular item. If the patient pays a higher premium the policy will cover more items. The fact that some policies require precertification reflects two factors. One is the amount that the patient pays for his insurance, and the other is the marketing fact that the insurance industry has developed data that allow them to sell these policies more easily to the purchasers. Basically, "it is the thing to do" to market a policy that contains a stipulation of precertification. This interaction is purely between the patient and his insurance company. It has little to do with the doctor-patient relationship.

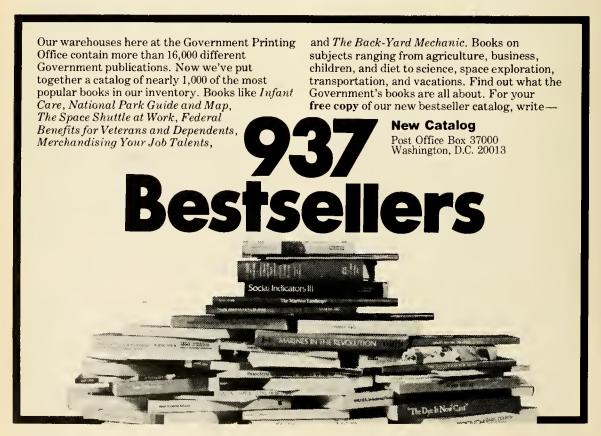
Medicine's mistake has been the gradual development of negotiations and interaction directly with the insurance companies. At first, it was done to help the patient, as the forms can get confusing. Over the years, the magnitude of the financial dealings between doctors and third party payors has tended to distort our professional relationship with our patients and has created the illusion that we have a primary relationship with the third party payors. I believe that some physicians believe that they are working for the insurance companies, and the unquestioned cooperation with the precertification and extension of days requirements is testimony of medicine's confusion with this issue.

I urge my fellow physicians to place the responsibility for handling the quirks of health insurance on the party that appropriately should handle it: the patients. It will be the complaints of the patients, not of the doctors, that will change any abuses by the third parties. The physician is not the customer, and the treatment you receive will not be the same as the treatment that the third parties will be forced to give to their customers, our patients.

If your patients cannot handle the necessary questions, you can supply the answers and give them all the help you can, but don't continue to elevate the physician-insurance company relationship beyond its appropriate boundaries. The true master of the physician is the patient. The maintenance of this relationship is vital.

It is appropriate that third party payors attempt to limit unnecessary health care expenditures. I am also certain that the hazy line between unnecessary and necessary expenditures is best drawn by physicians. I am also certain that patients will be better satisfied with this approach. Our continued tacit acceptance of third party payors as the "boss" only allows them to draw these lines where they desire. We must keep in mind that it is the patients who are paying us for our services, and not the third parties.

For the future of medicine, I would cast my lot with the patients. It is they who will demand and pay for services. Involving your patients in the benefits they have paid for is the surest way to make the insurance companies listen. I would begin to reestablish the primacy of the patient again, for I believe that the very future of medicine depends upon it. The medicine will be bitter, but the cure will be the end of many of the potential abuses in benefits that lie ahead if we continue to allow the third parties unwarranted inroads into medical practice. It is the duty of each physician to ask his patients to obtain their own precertification. The medicine may be bitter, but the cure is worth it.



**ETHICS** 

## Community Resources in Bioethics: A New Initiative for North Carolina

George Barrett, M.D., and John Lincourt, Ph.D.

THE ethical decisions of a society reflect its collective social values. They should, therefore, be arrived at by a collective process — one that includes as many members of society as possible. Although this is a laudable goal, it involves many obstacles especially when applied to technical and controversial areas. In no area is this more evident than in biomedical ethics.

One major obstacle is educational. How is it possible for the public to participate in the bioethical debate in a reasonable manner when the issues are vexing even for the experts? Thus, it should not be surprising to find, as Holmes did, "that although some inclusion of the public in the decision-making process for bioethical dilemmas has occurred, this has been episodic." Things appear to be changing. Reports from Minnesota, Oregon and elsewhere describe local and statewide initiatives to develop organizations whose purpose is to raise public and professional awareness of bioethical issues. It is hoped that this will lead to informed participation and shared responsibility on such matters.

#### The Charlotte Story

With support of the Mecklenburg County Medical Society and with cooperation from the major hospitals in the Charlotte area, the Bioethics Resource Group Ltd. came into being. The goals of the organization are clearly described in its Mission Statement:<sup>4</sup>

Advances in medical technology now allow society to make choices that were unheard of a few years ago. Increasingly, these choices raise ethical issues involving patient privacy, the quality of life, and conflicts between rising health-care costs and the humane, equitable allocation of medical resources. To assist the medical community and the general public in understanding and working through such issues, the Bioethics Resource Group Ltd. was organized as a broad-based volunteer council for the purpose of:

From Bioethics Resource Group, c/o Professor Lincourt, Department of Philosophy, The University of North Carolina, Charlotte 28223.

- heightening community awareness of bioethical issues by inviting scholars, researchers and other qualified individuals to present public programs on such issues and by making speakers, reading material and other relevant matter available to the general public;
- assisting people in health-care and allied professions in recognizing bioethical issues and in keeping abreast of developments that relate to bioethical issues;
- encouraging the establishment of ethics committees in hospitals and other health-care institutions and offer them support and guidance on policies and decisions that are bioethical in nature.

Since it is a community, voluntary, non-profit organization, it makes an implicit declaration, namely, that it is available to all, that it will not profit from the patient's need or medicine's current difficulties and that its selfinterests will remain subservient to the community. These convictions have several important facets: 1) They illustrate again the "Charlotte Way" of dealing with local problems, i.e., a group of concerned citizens assembled to identify and work through an issue. 2) They underscore the fact that although the medical community led the way in this local initiative in bioethics, it has no intention of dominating the direction or philosophy of the Group. 3) And although the major primary care hospitals in Charlotte support the organization financially, their support does not entail the endorsement of individual hospital policies or practices. The Bioethics Resource Group is not a political entity but rather an educational one.

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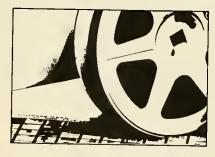
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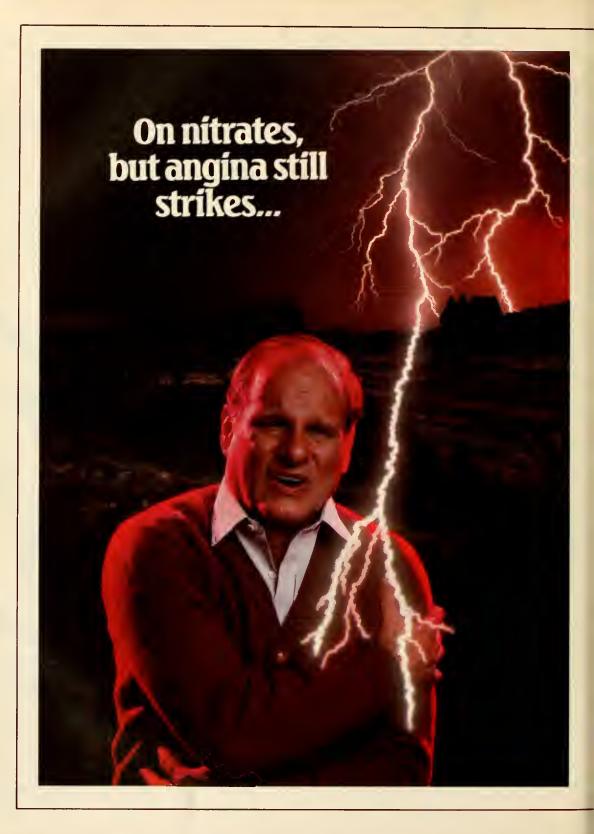
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Elevations of transaminases with and without concomitant elevations in alkaline phosphatase and bilirubin have been reported. Such elevations may disappear even with continued treatment; however, four cases of hepatocellular injury by verapamil have been proven by rechallenge. Periodic monitoring of liver function is prudent during verapamil herapy Patients with athal flutter or fibrillation and an accessory AV pathway (e.g. W-P-W or L-G-L syndromes) may develop increased antegrade conduction across the aberrant pathway bypassing the AV node, producing a very rapid ventricular response after receiving ISOPTIN (or digitalis). Treatment is usually D.C.-cardioversion, which has been used safely and effectively after ISOPTIN Because of verapamils effect on AV conduction and the SA node, 1° AV block and transient bradycardia may occur. High grade block, however, has been infrequently observed. 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Most adverse effects responded well to dose reduction and only rarely was verapamil discontinued **Precautions:** ISOPTIN should be given cautiously was verapamil discontinued Precautions: ISOPTIN should be given cautiously to patients with impaired hepatic function (in severe dysfunction use about 30% of the normal dose) or impaired renal function, and patients should be monitored for abnormal prolongation of the PR interval or other signs of excessive pharmacologic effects. Studies in a small number of patients suggest that concomitant use of ISOPTIN and beta blockers may be beneficial in patients with chronic stable angina. Combined therapy can also have adverse effects on cardiac function. Therefore, until further studies are completed, ISOPTIN should be used alone, if possible. If combined therapy is used, close surveillance of vital signs and clinical status should be carried out. 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Until further data are obtained, combined ISOPTIN and quinidine therapy in patients with hypertrophic cardiomyopathy should probably be avoided, since significant hypotension may result. Clinical experience with the concomitant use of ISOPTIN and short- and long-acting nitrates suggest beneficial interaction without undesirable drug interactions. Adequate animal carcinogenicity studies have not been performed. One study in rats did not suggest a tumorigenic potential, and verapamil was not mutagenic in the Ames est. Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. This drug should be used during pregnancy, labor and delivery only if clearly needed. It is not known whether verapamil is excreted in breast milk; therefore, nursing should be discontinued during ISOPTIN use. Adverse Reactions: Hypotension (2.9%), peripheral edema (1.7%), AV block: 3rd degree (0.8%), bradycardia: HR < 50/min (1.1%), CHF or pulmonary edema (0.9%), dizziness (3.6%), headache (1.8%), fatigue (1.1%), constipation (6.3%), nausea (1.6%), elevations of liver enzymes have been reported. (See Warnings.) The following reactions, reported in less than 0.5%, occurred under circumstances where a causal relationship is not certain: ecchymosis, brussing, gynecomastia, psychotic symptoms, confusion, parestine; associated and proper to the supplied of the proper of the propertion of the properties of th under circumstances where a causal relationship is not certain: ecchymosis, bruising, gynecomastia, psychotic symptoms, confusion, paresthesia, insomnia, somnolence, equilibrium disorder, blurred vision, syncope, muscle cramp, shakiness, claudication, hair loss, macules, spotty menstruation. 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## Do the Inefficiencies of the Legal System Contribute to Higher Costs?

Lloyd F. Redick, M.D.

MUCH is being written, said and legislated regarding the high cost of medical care, and questions are being asked regarding the ability to pay for or financially support medical care and related technologic advances. Legal "care" is likewise increasing in cost at an alarming rate: the costs of the court system, the need for more courts, judges, and support personnel, not to mention the increasing number of suits being filed. Certainly, much of this is caused by an increasingly litigious society, along with pressures to "do all that can be done." The net result is an increased cost to a profession or business and increased liability insurance premiums. Many small businesses are being forced to close, professional liability insurance is more difficult to obtain, and even municipalities are finding it difficult to obtain and finance liability insurance.

Where do some of these increased costs arise? In what way may some reduction of these costs be attained? If the legal system is operating efficiently and optimally, correct decisions should be made at the first ruling of a review board or at the first trial. Appeals would be possible but they would be few in number because the appeal court would find few mistakes in properly conducted procedures. If the legal system is not efficient and well conducted, appeals will be frequent and reversals of decision common. May this be part of the problem?

Various court cases and decisions are published as abstracts in the *American Medical News*, a weekly news publication of the American Medical Association. These abstracts were reviewed and further categorized beginning with the March 22, 1985 issue through the November 15, 1985 issue. Cases that involved theoretical aspects, i.e., blood transfusion for refusers, withholding of life support in hopeless situations, were not included, nor were a few cases in which the decisions were too ambiguous or in-adequately described to be assessed by the reviewer. Case reports from other sources were initially considered but dropped as they often were limited in subject and presented the possibility of duplication.

A total of 188 case abstracts were reviewed and analyzed for this report (table 1). They included 20 in which the decision of a legally constituted board was appealed to a trial or other court; the remaining 168 were initiated in a trial court. The cases were further subdivided into categories by type — medical malpractice, contractural dis-

putes, fee disputes, libel, criminal, suits regarding privilege in communication or medical aspects (Priv-1), privileges regarding practice, i.e. licensure, hospital privileges, practice location, etc. (Priv-2), and miscellaneous (table 1). All cases involved a health professional (not necessarily a physician) or a health professions institution.

#### Results

All 20 of the cases reported involving board decisions (table 1) were appealed, perhaps reflecting that those not appealed were not reported. However, only 60% of the board decisions were supported on appeal, and 40% reversed.

Of cases in trial courts, 81% were appealed, with 58.8% of the initial decisions supported, 32.4% reversed, and 10.3% of varied decision (i.e., more than one issue, partial support/reversal), and 33.8% were returned for retrial or further proceedings. The range for cases sustained was from 37.5% in cases involving fees to 100% for criminal cases.

#### Discussion

There are several aspects of this study that raise the question of its validity. The case abstracts reviewed had been previously selected, but on what basis? They mostly have some relevant interest to physicians. Was the decision a factor in selection, the fact of an appeal? We do not know the total number of cases going to trial or presented to boards, the *n* or total population of statistical use. Therefore the percentages of appealed cases and the percentages of supported and reversed decisions, etc., are based on these preselected cases. This may reflect a much higher incidence of appeal than actually occurred if based on all cases. It should be noted that the author is untrained and inexperienced in legal matters and procedures, which may further bias the results shown.

On the other hand, the number of appealed cases as abstracted, 80%, suggests that there is a level of dissatisfaction with the first decision, or a perceived element of error, or some other moving force to carry the case to further levels for decision. Certainly this has its merit in the legal system as developed in this country. If one has suffered a perceived wrong, and an initial trial has not seemingly rendered an appropriate decision, the right to request or demand further review must be respected. There was a surprisingly high number of reversals of lower court decisions, 32.4%, or partial decisions, 10.3%, and the

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Table 1
Case Abstracts Reviewed

Туре	Total No. (% of Total)	No. Appealed (% of type)	Dec. Sust. (% Sust.)	Dec. Rev. (% Rev.)	Other Dec. (% Other)	Retrial (% of Retrial)
Med Mal	85	68	40	20	8	24
	(45.2%)	(80.0%)	(58.8%)	(29.4%)	(11.8%)	(35.3%)
Contracts	34	31	19	12	1	10
	(18.1%)	(91.2%)	(61.3%)	(38.7%)	(3.2%)	(32.3%)
Priv-1	11	9	7	1	1	2
	(5.9%)	(81.8%)	(77.8%)	(11.1%)	(11.1%)	(22.2%)
Priv-2	23	21 ´	10	9 ′	2	3 ′
	(12.2%)	(91.3%)	(47.6%)	(42.9%)	(9.5%)	(14.3%)
Fees	10	8	3 ′	4	1	3
	(5.3%)	(80.0%)	(37.5%)	(50.0%)	(12.5%)	(37.5%)
Libel	5	4	3	1	Ò	ò
	(2.7%)	(80.0%)	(75.0%)	(25.0%)	_	_
Criminal	5 ′	4	4	Ò	0	0
	(2.7%)	(80.0%)	(100.0%)	_	_	_
Tax	2 ′	ò	Ò	0	0	0
	(1.1%)	_	_	_	_	_
Misc.	13	11	6	4	1	4
	(6.9%)	(84.6%)	(54.5%)	(36.4%)	(9.1%)	(36.4%)
Totals	188	156	92	51	14	46
		(83.0%)	(59.0%)	(32.7%)	(9.0%)	(29.5%)
Trial Court	168	136	80	44	14	46
	(89.4%)	(81.0%)	(58.8%)	(32.4%)	(10.3%)	(33.8%)
Boards	20	20	12	8	Ò	Ó
	(10.6%)	(100.0%)	(60.0%)	(40.0%)	_	_

Abbreviations: Med Mal = medical malpractice cases; Contracts = contractural problems; Priv-1 = privileges in patient or other medical contexts; Priv-2 = privileges regarding practice, licensure, etc.; Fees = fee problems; Libel, Criminal, Tax = as labelled; Misc. = miscellaneous; Boards = official capacity boards; Dec. Sust. = decisions of board or lower court sustained; Dec. Rev. = decision reversed; Other dec. = variable or partial decisions, usually with new trial ordered.

number of cases in which retrial or other further proceedings were mandated, 33.8%.

If the number of reversals was small, the incidence of appeals would probably be reduced because an appeal would not be worth the time and effort. The question is: Why are there so many reversals of decisions? Are attorneys poorly prepared? Are judges poorly prepared? Are errors in the proceedings involved? Are juries and the potential of prejudicial, emotional, or other aspects important considerations? In medicine, we often do not have a second or third chance at decisions; for example, how often can one remove an appendix from one patient? Conversely, federally sponsored and third party programs are increasingly requiring "second opinions" for various problems and procedures. What happens when the two opinions disagree? Shall there be an appeals court for second opinions? Or shall the least expensive approach (for the third party payor) be used?

The legal system is largely based on precedent, that is, cases of similar nature in the past may determine decisions today, providing that the past decisions were in agreement. But many are not in agreement, so precedents can be found for both sides of an issue. Scientific principles of proof are not available to define these principles. Legal cases may involve slight variations, "shades of gray," rather than definite entities, "black and white," yet decisions are often rendered as if definitive. The making black and white of shades of gray may enhance further appeal. This

may also explain why one decision is made one way, another the opposite, and precedent set for both sides of an issue. Therefore, each case may be decided on its "own merit" which may be good or bad, depending on whose ox is being gored. For examples of this aspect, one need look only at decisions of the Federal Supreme Court, which are often split, such as 5 to 4, over an issue.

If errors are being made, how can these be prevented? A physician who makes errors may have serious problems with patient care and survival, and may face licensure and staff privilege problems, not to mention professional liability suits. Can courtroom errors be reduced? Can juries be better prepared and instructed? We know that attorneys are aware of "good" and "poor" jurors by experience profiles, and will attempt to achieve an advantageous jury at selection time. Jury awards of damage vary widely for similar levels of injury, and the element of emotional impact may relate to these decisions.

The cost of appeals, reversals, and retrials certainly adds considerably to the legal costs of the country. Costs to governmental bodies for providing space, judges, and support personnel are ever increasing. Appeals courts have had to be expanded to handle the increasing case load, and if not, the time lapse between filing suit and a decision rendered is further increased. For example, a congressional subcommittee is considering expansion of the Federal Supreme Court system to handle an increased workload, which has risen from about 1500 cases per year to over 5000

cases per year within the last decade. The time spent waiting for first trial is often quite long. Additional waiting for appeal processing may affect financial aspects of the parties involved. Retrials may not be as readily accomplished as witnesses and participants may become unavailable, die, or change.

How much may the appeals process add to an attorney's income, and does this have an influence? Competition is supposed to reduce price (= costs) in the marketplace. But would an oversupply of attorneys, as is suggested, result in reduced costs, or more suits being filed, and more appeals? The overall causes of increased legal actions (suits) has not been widely addressed, nor ready solutions found. I have not noted a widespread concern for the increase in appeals, the resultant decisions, the retrials, and the further costs these entail.

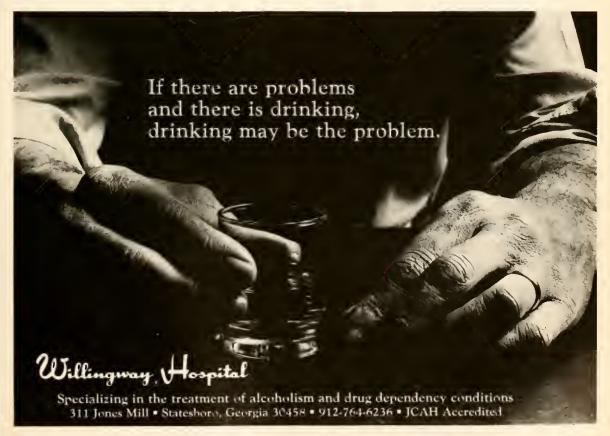
Arbitration panels have been suggested as a means to

reduce cases going to court trial. Instead of helping, arbitration panels may only add a step to the process if the panel decisions are appealed. Whether arbitration panels would have a significant impact has yet to be determined, and further evaluation will be necessary.

This study suggests that the number of legal decisions appealed is quite high. The incidence of reversal of first decisions and retrial is disturbing. Can the legal system establish procedures to reduce the error rate or otherwise reduce the number of appeals and reversals? Accomplishing this should reduce costs and increase productivity of the court systems. These issues do not appear to be addressed by the legal profession, yet much of the costs are borne by the public.

#### Reference

1. Sen. John East Newsletter, December 1985



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#### IN STATE

#### June 15-17

Surgery for Coronary Artery Disease

Place: Durham

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

ham 27710. 919/684-6878

What's New and Old in Gl Disease

Place: Sanford

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Carthage Street, Sanford 27330. 919/774-6518 Info:

#### June 19-21

Seaboard Medical Association of North Carolina and Virginia Annual

Session

Kill Devil Hills Place:

Julian R. Taylor, M.D., Box 10387, Raleigh 27605. 919/821-Info:

Diabetic Retinopathy and the Dye Laser

Place:

Info: Southern Eye Associates, 3320 Executive Drive, Raleigh 27609.

Contact Lenses and Refractive Surgery: Where Is The Balance?

Place.

Wrightsville Beach 10.5 hours Category I AMA Credit:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878 Info:

#### July 4-6

Sports Medicine Symposium

Place: Wrightsville Beach

\$30 Fee:

Alan Skipper, NCMS, Box 27167, Raleigh 27611. 919/833-Info:

28th Annual Postgraduate Course/Morehead Symposium Place: Atlantic Beach

26 hours Category I AMA, 24.5 prescribed hours AAFP Credit:

Fee:

Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

ham 27710. 919/684-6878

#### July 9-22

Reconstructive and Cosmetic Surgery

Credit:

25 hours Category 1 AMA Linda Mace, Box 3707 DUMC, Durham 27710. 919/684-8111

Cost of Medical Care

Place: Sanford

Info: Robert S. Cline, M.D., Central Carolina Hospital, 1135 Car-

thage Street, Sanford 27330. 919/774-6518

#### July 28-August 1

9th Annual Radiology Postgraduate Course

Place: Atlantic Beach

18 hours Category I AMA Credit:

Fee: \$350

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### August 8-10

Family Physicians Weekend

Wrightsville Beach

6 hours

Mary Anna Hendley, NC Academy of Family Physicians, Box 20146, Raleigh 27619. 919/781-6467 Info:

#### August 14-15

Annual Highland Hospital/Duke Psychiatry Conference

Place: Asheville

Credit: 11 hours Category 1 AMA

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

ham 27710. 919/684-6878

Psychiatry and the Acute Care Hospital Place: Sanford

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Car-Info:

thage Street, Sanford 27330, 919/774-6518

#### September 10

Eighth Annual Health Law Forum

Place: Greenville

Fee: \$125

Credit: 8 hours Category I AMA

Office of CME, ECU School of Medicine, Box 7224, Greenville Info:

27835-7224, 919/758-5200, ext 208

#### September 12

Allocation of Health Care for Children

Greenville

Loretta Kopelman or John Moskop, 919/757-2797

#### September 17

Nuclear Hazards and Medical Care

Place:

Robert S. Cline, M.D., Central Carolina Hospital, 1135 Car-

thage Street, Sanford 27330, 919/774-6518

#### September 21-24

Basic Clinical Teaching Skills

Place: Rougemont

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Durham 27710. 919/684-6878

#### October 6-10

Microsurgery Workshop

Place: Durham

Credit: Info:

40 hours Category I AMA Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

ham 27710. 919/684-6878

#### OUT OF STATE

#### June 19-22

Annual Duke Conference: Contemporary Developments in Anesthesiol-

ogy Place: Hilton Head Island, SC

Credit: 17 hours Category 1 AMA

Info: Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-

ham 27710. 919/684-6878

June 24-29

Second Annual Advances in Internal Medicine

Hilton Head Island, SC

18.5 hours Category I AMA, 17 prescribed hours AAFP Cynthia C. Easterling, Office of CME, Box 3108 DUMC, Dur-ham 27710. 919/684-6878 Credit:

June 30-Juty 5

Midsummer Family Practice Digest

Place: Myrtle Beach, SC Credit: 30 hours AAFP

Info: Mary Anna Hendley, NC Academy of Family Physicians, Box

20146, Raleigh 27619. 919/781-6467

July 16-20

Seminar on Preventive Medicine: Nutrition Place: Hilton Head Island, SC

Credit:

12 hours Category I AMA Harold D. Schutte, 53 S. French Broad, Asheville 28801, 704/ Info:

258-0969

July 29-30

Advanced Neurosonology Seminar Place: Snowmass, CO

Frederick Kremkau, M.D., Bowman Gray School of Medicine,

Winston-Salem 27103. 919/748-4505

July 31-August 2

Advanced Applied Ultrasound in Obstetrics

Snowmass, CO Place:

Frederick Kremkau, M.D., Bowman Gray School of Medicine,

Winston-Salem 27103, 919/748-4505

September 11-13

Doppler Echocardiography Seminar

Tarpon Springs, FL Credit: 14 hours Category I AMA

Fee: \$350

Info: Frederick Kremkan, M.D., Bowman Gray School of Medicine,

Winston-Salem 27103, 919/748-4505

October 17

Selected Topics in Pediatrics Place: Norfolk, VA

Jean E. Shelton, M.D., 800 West Olney Road, Norfolk, VA 23507, 804/628-7179

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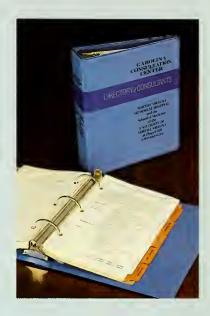
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#### Letters to the Editor

#### To the Editor:

The fine article on the methemoglobinemia of a V.A. Hospital patient reported in your March 1986 (NCMJ 1986;47:109-11) issue was interesting and timely.

It might be of interest to area physicians to know that the Duke Blood Gas Laboratory never reports calculated oxygen saturations, but performs direct measurements on all blood gas samples sent to the laboratory. The state of the art instrumentation allows us to measure oxyhemoglobin, reduced hemoglobin, carboxyhemoglobin, and methemoglobin on all samples  $\pm 0.5\%$  saturation.

This allows immediate definitive diagnosis of carbon monoxide poisoning and the rarer methemoglobinemia on all Duke patients referred to the Blood Gas Laboratory.

The medical director is available and pleased to assist in the care of these patients in anyway he can.

> Kenneth D. Hall, M.D. Blood Gas Laboratory Duke University Medical Center Durham 27710

#### Vitamin B<sub>12</sub> Deficiency

#### To the Editor:

The perplexity of the editor and the potential damage to the scalps of Drs. Matchar and Feussner while interpreting laboratory findings in patients suspected of vitamin B<sub>12</sub> deficiency (NCMJ 1986;47:118-120) might be lessened if the nature of the material being measured in the serum B<sub>12</sub> assay is kept in mind. In most persons most serum B<sub>12</sub> is bound to transcobalamin I (TCI, cobalophilin), a glycoprotein of uncertain function. B<sub>12</sub> in this form is not readily utilized and the factors affecting the quantity of this protein in plasma and the quantity of B<sub>12</sub> bound to it are incompletely understood. They are affected by many factors other than the size of B<sub>12</sub> stores and it is perhaps fortuitous that B<sub>12</sub> in this form is usually subnormal in clinical B<sub>12</sub> deficiency. B<sub>12</sub> is delivered to most tissues bound to transcobalamin II (TCII) but at any given time only a small fraction of serum B<sub>12</sub> is so bound and is extremely labile. Persons with a congenital absence of TCI have low serum B<sub>12</sub> levels but no B<sub>12</sub> deficiency; persons with congenital absence of TCII have normal serum B<sub>12</sub> levels and severe B<sub>12</sub> deficiency.

The Schilling test is of limited practical value in identifying patients with  $B_{12}$  deficiency. It tests  $B_{12}$  absorption but is fraught with pitfalls of which fecal contamination of urine specimens is but one. Impaired renal function, incomplete urine collections, administration of other radioactive isotopes without knowledge of the laboratory measuring urinary radioactive  $B_{12}$ , and concomitant administration of drugs that transiently impair  $B_{12}$  absorption are some of the numerous things that make the Schilling test difficult except in highly controlled conditions. If done it should be remembered that it is a test of  $B_{12}$  ab-

sorption at a particular time. An abnormally low result does not prove the existence of  $B_{12}$  deficiency.

The deoxyuridine suppression test is precisely what the editor calls for in his note. It has its own set of pitfalls and as the authors point out, is not necessary or practical in a general clinical setting.

In the final analysis the clinician, not the laboratory, must judge whether  $B_{12}$  deficiency exists. Most  $B_{12}$  deficiency in the United States results from gastric mucosal atrophy. A test of the ability of the stomach to secrete acid is of greater practical value in making this judgment than any of the tests mentioned in the paper of Drs. Matchar and Feussner.

J.G. Palmer, M.D. Dept. of Medicine University of North Carolina School of Medicine Chapel Hill 27514

#### The authors respond:

#### To the Editor:

Low serum B<sub>12</sub> assay results often do not correlate with response to treatment because many patients with low B<sub>12</sub> levels are not vitamin B<sub>12</sub> deficient. Total serum B<sub>12</sub> only indirectly reflects tissue levels of the vitamin. We agree with Dr. Palmer that a plausible explanation for this discrepancy is acquired or genetic variation in vitamin B<sub>12</sub> transport protein levels — in particular transcobalamin I (TC I), one of the so-called R-binders. However, only in rare cases have low levels of TC I been shown to be responsible for "false abnormal" B<sub>12</sub> assay results. It is not at all clear that the many unexplained low serum B<sub>12</sub> results we see in our day to day practice are due to low levels of a B<sub>12</sub> binding protein. Transcobalamin II (TC II) is the B<sub>12</sub> binding protein with clear physiologic importance and one would expect saturated TC II to be the quantity which most closely reflects tissue B12 levels. Some preliminary work using such an assay suggests that B<sub>12</sub> deficient patients have totally unsaturated TC II.2 This test may prove to be a significant improvement over conventional serum B<sub>12</sub> assays.

We must disagree with Dr. Palmer's statement that the Schilling test is of limited practical value. Although there are many circumstances in which a patient may have an abnormal Schilling test result and yet not be B<sub>12</sub> deficient, we have found that normal results rarely occur in the presence of deficiency. Simultaneous administration of radionuclides with and without intrinsic factor (as may occur with the dual Schilling test), and fecal contamination of the urine specimen are avoidable technical reasons for falsely normal Schilling results. Rarely, patients with frank dietary B<sub>12</sub> deficiency can have a normal Schilling result as can patients with impaired absorption of food-bound B<sub>12</sub> but normal absorption of crystalline B<sub>12</sub>. However

rare,<sup>3</sup> a normal Schilling test result in a patient with other evidence of  $B_{12}$  deficiency suggests that the patient can be treated with an oral  $B_{12}$  preparation. This information is a definite practical benefit of the test.

It is interesting that Dr. Palmer finds fault with the Schilling test and yet favors measuring gastric acid secretion. Not only does this fail to identify B<sub>12</sub> deficiency due to causes other than loss of parietal cells, achlorhydria cannot be considered diagnostic. Approximately half of elderly patients are achlorhydric, yet few would argue that all of these people are vitamin B<sub>12</sub> deficient.<sup>3</sup>

We would like to thank Dr. Palmer for his touching and somewhat unique concern for our scalps. We have found that while scalp scratching does not improve the accuracy of available tests for vitamin  $B_{12}$  deficiency, it does keep the confusion outside rather than inside the head.

David B. Matchar, M.D. John R. Feussner, M.D. Duke University Medical Center Durham 27710

#### References

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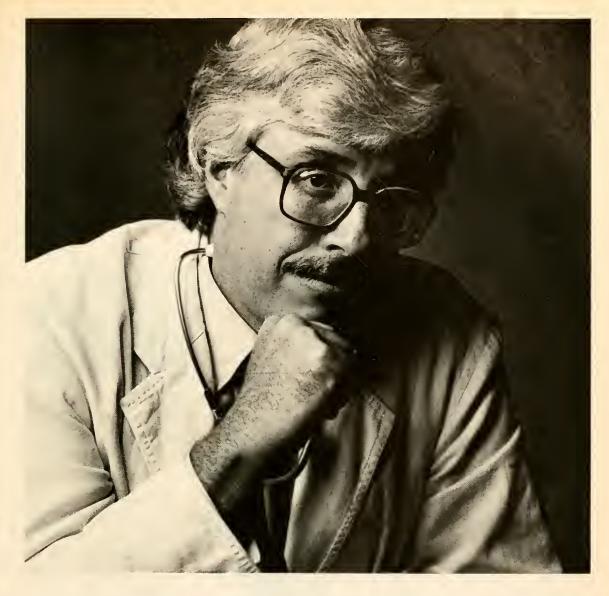


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## A defense against cancer can be cooked up in your kitchen.



Fruits, vegetables, and wholegrain cereals such as oatmeal, bran and wheat may help lower the risk of colorectal cancer.

Foods high in fats, salt- or nitrite-cured foods like ham, and



There is evidence that diet and cancer are related. Some foods may promote cancer, while others may protect you from it.

Foods related to lowering the risk of cancer of the larynx and esophagus all have high amounts of carotene, a form of Vitamin A which is in cantaloupes, peaches, broccoli, spinach, all dark green leafy vegetables, sweet potatoes, carrots, pumpkin, winter squash and tomatoes, citrus fruits and brussels sprouts.

Foods that may help reduce the risk of gastrointestinal and respiratory tract cancer are cabbage, broccoli, brussels sprouts, kohlrabi, cauliflower.

fish and

types of sausages smoked by traditional methods should be eaten in moderation.

Be moderate in consumption of alcohol also.

A good rule of thumb is cut down on fat and don't be fat.
Weight reduction may lower cancer risk. Our 12- year study of nearly a million Americans uncovered high cancer risks particularly among people 40% or more overweight.

Now, more than ever, we know you can cook up your own defense against cancer. So eat healthy and be healthy.

No one faces cancer alone.



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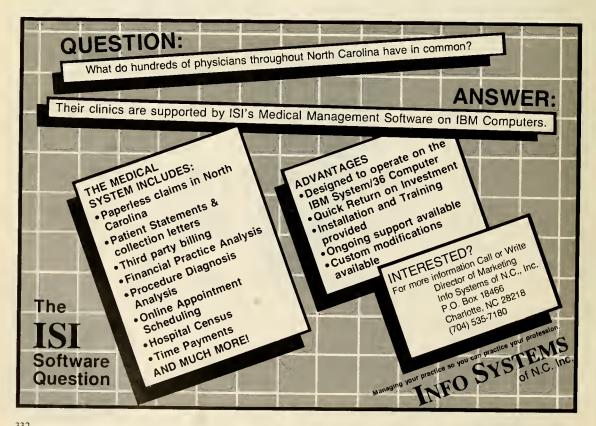
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- buy. Dr. Joe Henson, 1107 W. Friendly Avenue, Greensboro 27401. 919/274-1567.
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Before prescribing, see complete prescribing Information in SK&F CO. fiterature or *PDR*. The following is a brief summary.

This drug is not indicated for initial therapy of edema or hyperten-sion Edema or hypertension requires therapy titrated to the individual. If this combination represents the dosage so determined, its use may be more convenient in patient management. Treatment of hyper-tension and edema is not static, but must be reevaluated as con-ditions in each patient warrant.

Contraindications: Concomitant use with other potassium-sparing agents such as spirondactone or amilioride Further use in anuna, progressive renal or hepatic dysfunction, hyperkalemia, Pre-austing elevated serum potassium. Hypersensitivity to either component or other sulfonamidederived drugs

derived drugs. Warnings: Do not use potassium supplements, dietary or otherwise, unless flypakalemia develops or dietary intake of potassium is markedly impaired. It supplementary potassium is needed, potassium is markedly impaired. It supplementary potassium is needed, potassium tablets should not be used. Hyperkalemia can occur, and has been associated with cardiac irregularities. It is more likely in the severely ill, with urine volume less than one liter day, the elderly and diabettos with suspected or confirmed renal insufficiency. Periodically, serum K.\* levels should be determined I Hyperkalemia develops, substitute a thrazide alone, restrict K.\* intake. Associated widened QRS complex or arrhythmia requires prompt additional therapy. Thiszides cross the placental barrier and appear in cord olbod. Use in pregnancy requires weighing anticipated benefits against possible hazards, including letal or neonatal jaundice, thrombocytopenia, other adverse reactions seen in adults. Thiszides appear and triametrene may appear in breast milk. If their use is essential, the potient should stop nursing. Adequate information on use in children is not available. Sensitivity reactions may occur in patients with or without a history of allery or bronchial asthma. Possible exacerbation or activation of systemic tupus erythematosus has been reported with thiazide diuretics.

out a history of allergy or bronchial asthma Possible exacerbation of scitization of systemic tupus enythematosus has been reported with hiszade duretics

Precautions: The bioavailability of the hydrochlorothiazide component of Dyazide's about 50% of the bioavailability of the single entity; Theoretically, a patient transferred from the single entities of traintenent and hydrochlorothiazide and show a nicrease in blood pressure of titude retention Similarly, it is also possible that the lesser hydrochlorothiazide inbioavailability could lead to increased serum potassium levels However, extensive clinical experience with Dyazide's uggests that these conditions have not been commonly observed in clinical practice. Angiotensin-converting enzyme (AGE) inhibitors can elevate serum potassium; use with caution with Oyazide's ouperstimation experience with Oyazide's understimation of the properties of the control of

Increase the risk of influim function.

Adverse Reactions: Muscle cramps, weakness, dizziness, headache, dry mouth, anaphylaxis, rash, urticaria, photosensitivity, purpura, other dermatological conditions, nausea and vomiting, diarrhea, constipation, other gastrointestinal disturbances; postural hypotension (may be aggravated by alcohol, barbiturates, or narcotics). Necrotizing vasculitis, paresthesias, icterus, pancrealitis, xanthonisia and respiratory distress including pneuronitis and pulmonary edema, transient blurred vision, saladentis, and vertigo have occurred with thrazides alone Timatherene has been found in renal stones in association with other usual calculus components. Rare incidents of acute intersitial nephritis have been reported. Impotence has been reported in elev patients on "byzque" although a causal relationship has not been established.

Supplied: 'Oyazlde' is supplied as a red and white capsule, in bottles of 1000 capsules; Single Unit Packages (unit-dose) of 100 (intended for institutional use only); in Patient-Pak <sup>7M</sup> unit-of-use bottles of 100.

### In Hypertension\*... When You Need to Conserve K+

Remember the Unique Red and White Capsule: Your Assurance of SK&F Quality

Serum K<sup>+</sup> and BUN should be checked periodically (see Warnings and Precautions).



Potassium-Sparing

25 mg Hydrochlorothiazide/50 mg Triamterene/SKF

Over 19 Years of Confidence

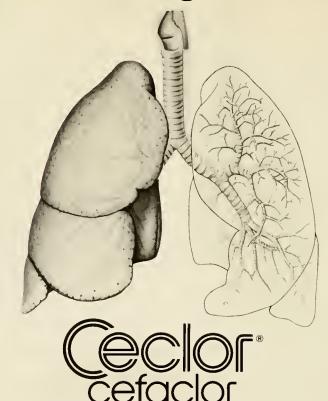
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### Consider the causative organisms...



#### 250-mg Pulvules® t.i.d. offers effectiveness against the major causes of bacterial bronchitis

Haemophilus influenzae, H influenzae, Streptococcus pneumoniae, Streptococcus pyogenes (ampicillin-susceptible) (ampicillin-resistant)

Note: Ceclor is contraindicated in patients with known allergy to the cephalosporins and should be given cautiously to penicillinallergic patients.

#### Ceclor (cefactor)

Summary. Consult the package literature for prescribing information.

Indications: Lower respiratory infections, including pneumonia, caused by susceptible strains of Streptococcus pneumoniae. Haemophilus influenzae, and S pyogenes (group A beta-hemolytic streptococci).

Contraindications: Known allergy to cephalosporins

Warnings: CECLOR SHOULD BE ADMIN-ISTERED CAUTIOUSLY TO PENICILLIN-SENSITIVE PATIENTS. PENICILLIN-SENSITIVE PATIENTS. PENICILLINS AND CEPHALOSPORINS SHOW PARTIAL CROSS-ALLERGENICITY POSSIBLE REACTIONS INCLUDE ANAPHYLAXIS

Administer cautiously to allergic

Pseudomembranous colitis has been reported with virtually all broad-spectrum antibiotics. It must be considered in differential diagnosis of antibiotic-

associated diarrhea Colon flora is altered by broad-spectrum antibiotic treatment, possibly resulting in antibiotic-associated colitis

#### Precautions:

- Discontinue Ceclor in the event of allergic reactions to it.
- Prolonged use may result in overgrowth of nonsusceptible organisms.

  Positive direct Coombs' tests have been reported during treatment with cephalosporins
- In renal impairment, safe dosage of Ceclor may be lower than that usually recommended. Ceclor should be administered with caution in such patients
- Broad-spectrum antibiotics should be prescribed with caution in individuals with a history of gastrointestinal disease, particularly colitis.
- Safety and effectiveness have not been determined in pregnancy, lactation, and intants less than one month old. Ceclor

Penicillin is the usual drug of choice in the treatment and prevention of streptococcal infections, including the prophylaxis of rheumatic fever. See prescribing information.

penetrates mother's milk. Exercise caution in prescribing for these patients. Adverse Reactions: (percentage of

Therapy-related adverse reactions are uncommon. Those reported include:

- · Gastrointestinal (mostly diarrhea): 2.5%.
- · Symptoms of pseudomembranous colitis may appear either during or after antibiotic treatment
- antibiotic treatment.

  Hypersensitivity reactions (including morbilliform eruptions, pruritus, urticaria, erythema multifume, serum-isckness-sike reactions): 1.5%, usually subside within a few days after cessation of therapy. These reactions have been reported more frequently in children than in adults and have usually occurred during or following a second course of therapy with Ceclor No serious sequelae have been reported. Antihistamines have been reported. Antihistamines and corticosteroids appear to enhance resolution of the syndrome
- Cases of anaphylaxis have been reported, half of which have occurred in patients with a history of penicillin allergy
- Other eosinophilia, 2%; genital pruritus or vaginitis, less than 1%.

#### Abnormalities in laboratory results of uncertain etiology

- Slight elevations in hepatic enzymes. Transient fluctuations in leukocyte count (especially in infants and children)
- Abnormal urinalysis; elevations in BUN
- or serum creatinine Positive direct Coombs' test
- Positive direct coolings test
  False-positive tests for urinary glucose
  with Benedict's or Fehling's solution and
  Clinitest\* tablets but not with Tes-Tape\*
  (glucose enzymatic test strip, Lilly)

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**EXCERPTS FROM A SYMPOSIUM** "THE TREATMENT OF SLEEP DISORDERS"8

> ... highly effective for both sleep induction and sleep maintenance

> > Sleep Loboratory Investigator Pennsylvania

onset of action is rapid...provides sleep with no rebound effect to agitate the patient the following day

> **Psychiatrist** California

... appears to have the best safety record of any of the benzodiazepines

> **Psychiatrist** California

After 15 years, the experts still concur about the continuing value of Dalmane (flurazepam HCI/ Roche). It provides sleep that satisfies patients... and the wide margin of safety that satisfies you.

The recommended dose in elderly or debilitated patients is 15 mg. Contraindicated in pregnancy.

DALMANE brand of

flurazepam HCI/Roche ®

sleep that satisfies

15-mg/30-mg capsules

References: 1. Kales J, et al. Clin Pharmiacol Ther 12 691-697, Jul-Aug 1971 2. Kales A, et al. Clin Pharmacol Ther 18 356-363, Sep 1975 3. Kales A, et al. Clin Pharmacol Ther 19 576-583, Moy 1976 4. Koles A, et al. Clin Pharma-col Ther 32.781-788, Dec 1982 5. Frost JD Jr, DeLucchi MR J Am Geratr Soc 27541-546, Dec 1979 **6.** Dement WC, et al. Behov Med, pp. 25-31, Oct 1978 **7.** Koles A, Kales JD. J Clin Psychophormocol 3 140-150, Apr. 1983 8. Tennant FS, et al. Symposium on the Treatment of Sleep Disorders, Teleconference, Oct 16, 1984 9. Greenblott DJ. Allen MD, Shader RI Clin Pharmacol Ther 21 355-361, Mor 1977



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information, a summary of which follows Indications: Effective in all types of insomnia characterized by difficulty in folling asleep, frequent nacturnal awakenings and/or early morning awakening, in patients with recurring insamnia or poor sleeping hobits, in ocute or chronic medical situations requiring restful sleep. Objective sleep laboratory dato have shown effectiveness for at least 28 consecutive nights of administration. Since insamnia is aften transient and intermittent, prolonged administration is generally not necessary or recommended. Repeated therapy should only be undertoken with oppropriate patient evaluation.

Contraindications: Known hypersensitivity to flurazepom HCl, pregnancy Benzadiazepines may cause tetal damoge when administered during pregnancy Several studies suggest an increased risk at congenital molformations associated with benzodiozepine use during the first frimester. Worn patients of the potential risks to the fetus should the passibility of be coming pregnant exist while receiving flurazepom. Instruct patients to discontinue drug prior to becoming pregnant. Con sider the possibility of pregnancy prior to instituting therapy

Warnings: Coution potients about possible combined effects with alcohol and other CNS depressants. An additive effect may occur if alcahal is consumed the day following use for nightlime sedation. This potential may exist for several days fallowing discontinuation. Coution against hazardaus accu potions requiring complete mental alertness (eg, aperating machinery, driving). Potential impairment of performance of such activities may accur the day tallawing ingestion. Not recommended tar use in persons under 15 years of age. Withdrawol symptoms rarely reported, abrupt discontinuation should be avoided with gradual topering of dosage for those patients on medication for a prolonged period of time. Use coution in administering to addiction-prone individuals or those who might increase dosage

Precoutions: In elderly and debilitated patients, it is recommended that the dosage be limited to 15 mg to reduce risk of oversedation, dizziness, confusion and/or ataxio. Consider patential additive effects with other hypnotics or CNS depressonts. Employ usual precautions in severely depressed patients, or in those with lotent depression or suicidal tendencies, or in those with impaired renal or hepatic function.

Adverse Reactions: Dizziness, drawsiness, lightheodedness staggering, ofaxio and falling have occurred, porticularly in elderly or debilitated potients. Severe sedation, lethargy, dis orientation and como probably indicative at drug intalerance or overdosage, have been reported. Also reported headache heartburn, upset stomach, nausea, vamiting, diarrhea, constipation, GI pain, nervousness, talkativeness, apprehension, irritability, weokness, polpitations, chest pains, bady and joint pains and GU complaints. There have also been rare occur rences of leukopenio, granulocytopenio, sweating flushes, difficulty in focusing, blurred vision, burning eyes, faintness hypotension, shortness of breath, pruritus, skin rash, dry mouth, bitter taste, excessive salivation, anarexia, euphoria depression, slurred speech, confusion, restlessness, halluci nations, and elevated SGOT, SGPT, total and direct bilirubins, and alkaline phosphatase, and paradoxical reactions, e gexcitement, stimulation and hyperactivity

Dosage: Individualize for maximum beneficial effect. Adults 30 mg usual dosage, 15 mg may suffice in some patients Elderly or debilitated patients 15 mg recommended initially until response is determined

Supplied: Copsules containing 15 mg or 30 mg flurazepam



## **#1 FOR SLEEP**

After more than 15 years of use, it's #1 for sleep that satisfies. Patients are satisfied because they fall asleep fast and stay asleep till morning. 1-8 And *you're* satisfied by the exceptionally wide margin of safety. 7-9 As always, caution patients about driving or drinking alcohol.

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